

Request for Project Proposals



**Solicitation Number: MTEC-19-01-BPTS
“Burn Patient Transfer System (BPTS)”**

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: November 30, 2018

***Proposal Due Date: January 4, 2019
Noon Eastern Time***

White Papers Are NOT Required

Table of Contents

| | | |
|-------|---|----|
| 1 | Executive Summary..... | 4 |
| 1.1 | The Medical Technology Enterprise Consortium..... | 4 |
| 1.2 | Purpose | 4 |
| 2 | Administrative Overview | 5 |
| 2.1 | Request for Proposals | 5 |
| 2.2 | Funding Availability and Type of Funding Instrument Issued..... | 5 |
| 2.3 | Proprietary Information..... | 6 |
| 2.4 | Offeror Eligibility | 6 |
| 2.5 | Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions..... | 7 |
| 2.6 | Nontraditional Defense Contractor Definition | 7 |
| 2.7 | Requirements..... | 7 |
| 2.8 | Cost Sharing Definition | 7 |
| 2.9 | MTEC Assessment Fee | 8 |
| 2.10 | Intellectual Property | 9 |
| 2.11 | Data Rights | 9 |
| 2.12 | IT Interface Requirements | 10 |
| 2.13 | Expected Award Date..... | 10 |
| 2.14 | Anticipated Proposal Selection Notification..... | 10 |
| 3 | Proposal | 10 |
| 3.1 | Proposal | 10 |
| 3.2 | Proposal Submission | 11 |
| 3.3 | Submission Format | 11 |
| 4 | Proposal Preparation Instructions | 11 |
| 4.1 | General Instructions..... | 11 |
| 4.2 | Technical Requirements..... | 12 |
| 4.2.1 | Technical Background | 12 |
| 4.2.2 | Specific Aims of RPP | 14 |
| 4.2.3 | Research Plan..... | 15 |
| 4.2.4 | Requirements..... | 18 |
| 4.2.5 | Project Deliverables | 19 |
| 4.3 | Preparation of the Proposal..... | 20 |
| 4.4 | Cost Proposal | 21 |
| 4.5 | Proposal Preparation Costs..... | 22 |
| 4.6 | Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use | 22 |
| 5 | Selection..... | 22 |
| 5.1 | Proposal Evaluation Process | 23 |
| 5.2 | Evaluation Factors..... | 23 |
| 5.2.1 | Evaluation Factor 1. Technical Approach | 24 |
| 5.2.2 | Evaluation factor 2: Potential for Transition and Commercialization | 25 |
| 5.2.3 | Evaluation Factor 3. Cost/Price..... | 25 |
| 5.3 | Best Value | 27 |

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

5.4 Definition of General Terms Used in Evaluations:..... 27
6 Points-of-Contact 27
7 Acronyms/Abbreviations 29

1 Executive Summary

1.1 The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production.

*Note: Pending successful completion of the Tele-Sleep effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” government contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

1.2 Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the Joint Program Committee – 1 (JPC-1)/Medical Simulation and Information Sciences Research Program (MSISRP). The management of this effort will occur under the Medical Simulation and Information Systems (MSIS) Research Program/Joint Program Committee (JPC-1) Fort Detrick, MD JPC-1/MSISRP.

The goal of this research is to research, develop, and test a web based, and mobile app-accessible, open architecture cloud-based system to track capacity and improve the logistics of burn patient/trauma patient triage and transfer in and between military and civilian treatment facilities in the event of a war, disaster, nuclear or other mass casualty with large numbers of burn patients. Following a military or civilian mass casualty or disaster event, military treatment facilities would experience a significant increase in burn patient volume. Burn injuries are rarely isolated events; typically there is some type of associated trauma along with a burn injury, thus inclusion of trauma bed resources is desirable. There is only one military Burn Unit, the US Army

Institute of Surgical Research in San Antonio, TX. While able to expand capacity in the event of a mass casualty event and depending on the geographic area(s) involved in an event, bed capacity could easily be overwhelmed. The ability to maximize efficiency and effectiveness of triage and subsequent care would be critical to the management of an overwhelming surge in burn patient volume and intensity. This effort aims to conduct research and development of a burn/trauma patient transfer system that would provide a platform for reporting immediate and surge burn/trauma bed availability across the U.S. and among NATO partners, and electronically match patient and bed location and match patient acuity with open beds at clinical burn facilities nearby.

2 Administrative Overview

2.1 Request for Proposals

Each MTEC research project proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 3 of this request and must be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at www.mtec-sc.org. **White papers are not required for this RPP.** The Government reserves the right to award Proposals received from this RPP on a follow-on prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

2.2 Funding Availability and Type of Funding Instrument Issued

The U.S. Government (USG) currently has available approximately \$2.75M for Fiscal Years (FY) 18 & 19. The period of performance is not to exceed 36 months.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

It is expected that MTEC will make one award to a qualified team to accomplish all tasks. If a single proposal is unable to sufficiently address the entire scope of this RPP's technology objectives (outlined in section 4), several Offerors may be asked to work together. In a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (pOTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the pOTA between the USG and MTEC. Subsequently, any proposal that is selected for award will be funded

through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the Proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

2.3 Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Proposal and the subsequent agreement administration if the Proposal is selected for award. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.4 Offeror Eligibility

Offerors must be MTEC Members in good standing.

2.5 Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening. Please see the MTEC PPG and RPP (Section 5) for additional details.

2.6 Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.7 Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor; (2) proposes a nontraditional defense contractor as a team member/subcontractor; or (3) it is a nonprofit research institution, the Offeror must submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* includes:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment
4. Causing a material reduction in cost or schedule, and/or Improvement in performance

2.8 Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost,

labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

Cash Contribution

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

2.9 MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

2.10 Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.11 Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, then the Proposal should discuss data rights associated with each item,** and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

| Technical Data or Computer Software to be Furnished with Restrictions | Basis for Assertion | Asserted Rights Category | Name of Organization Asserting Restrictions | Milestone # Affected |
|---|---------------------|--------------------------|---|----------------------|
|---|---------------------|--------------------------|---|----------------------|

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| | | | | | |
|-----------------------|------|---|---------------------------|------------------|------------------------|
| Software XYZ | | Previously developed software funded exclusively at private expense | Restricted | Organization XYZ | Milestones 1, 3, and 6 |
| Technical Description | Data | Previously developed exclusively at private expense | Limited | Organization XYZ | Milestone 2 |
| Technical Description | Data | Previously developed with mixed funding | Government Purpose Rights | Organization XYZ | Milestone 2 |

2.12 IT Interface Requirements

Any technology-based research products/prototypes (such as devices, mobile apps, software, IT infrastructure, etc.) that expect to interact with military health IT systems should conform with accepted industry and DoD Information Management/Information Technology standards for interoperability, cybersecurity, as well as the DoD Architecture Framework (DODAF) and viewpoints. Additional points are:

1. Any products expected to provide data to the new DoD Military Electronic Health Record (MHS Genesis, which is the military version of Cerner Millenium commercial off the shelf electronic health record) should be aimed toward meeting the Health Level 7 (HL7) and Fast Healthcare Interoperability Resources (FHIR) standards in order to ultimately provide integration with MHS Genesis.
2. All software-based research products including computer code, software code, data and meta-data should be able to be uploaded to standards-based electronic repositories.
3. The approved DoD Mobile Solution is Samsung’s Android mobile phone and tablet.

2.13 Expected Award Date

Offeror should plan on the period of performance beginning April 15, 2019 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.14 Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors.

3 Proposal

3.1 Proposal

Full Proposals in response to this RPP must be received by the date on the cover page of this

RPP. Proposals received after the time and date specified will not be evaluated.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format provided in the MTEC PPG is mandatory. MTEC will post any general questions received and corresponding answers (without including questioners proprietary data) on the Members-Only MTEC website. The Government will evaluate Proposals submitted and will select Proposals that best meet their current technology priorities using the criteria in Section 6.

3.2 Proposal Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

MTEC membership is required for the submission of a Proposal. Offerors must be MTEC Members in good standing. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by **December 14, 2018**.

Do not submit any classified information in the proposal submission.

3.3 Submission Format

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces with MTEC's submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.**

4 Proposal Preparation Instructions

4.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two separate volumes and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The Proposal format provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC-19-01-BPTS). Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment

Schedule which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone, and any cost share, if applicable.

The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

4.2 Technical Requirements

4.2.1 Technical Background

In April 2017, the Operation Gotham Shield disaster exercise was carried out in New York/New Jersey/Northeast U.S. region under the U.S. Federal Emergency Management Agency (FEMA) leadership. The Scenario was a 10 KT nuclear device detonation causing 2000 burn casualties. The American Burn Association (ABA) response was led by Dr. Colleen Ryan of Massachusetts General Hospital, who was the Organization and Delivery of Burn Care committee chair. This exercise involved activation of the national burn bed reporting system (which was basically a query via e-mail), and when it became apparent that the open burn beds did not meet demand, the American College of Surgeons Committee on Trauma were asked to determine the number of open trauma beds. As part of this effort, activation of the DoD was not exercised to move these patients via the U.S. Air Force as per the National Disaster Medical System (NDMS). There is a large and urgent gap in burn bed supply and real-time capacity planning capabilities in the event of a large burn disaster, and the Operation Gotham Shield exercise confirmed this. The topic has visibility by the ABA and was discussed at the ABA's National Leadership Conference in February 2018.

The USAISR is the only DoD/military burn center, and is located in San Antonio, TX. The USAISR devised a system of transferring burn casualties before the start of Operation Iraqi Freedom (OIF)/Operation Enduring Freedom (OEF) in anticipation of numerous casualties. The premise was that USAISR would take all patients with chemical burns and patients with non-chemical burns would be transferred to an ABA-verified Burn Center nearest to each patient's home of record. It was sanctioned by the ABA, whose organization had most of the U.S. Burn Centers enrolled in the program. The Veterans Administration (VA), serving as the national emergency hospital management system, updated their burn bed availability/capacity once every 1 to 2

months, while the USAISR system would update bed capacity daily. Fortunately, the actual number of burn casualties during OIF/OEF was nowhere near the estimated number. That said, the system USAISR devised was operational the first day of the war and continued in operation until there was a determination that the numbers estimated and all burn casualties requiring an ABA-verified Burn Center could be handled at the USAISR.

The system worked as follows:

- a. The USAISR queried all the ABA-verified Burn Centers in the U.S. to determine if they wanted to participate or not. Each participating Center then submitted the capacity of its Burn Centers, including ICU beds and non-ICU (step-down) beds. This query from the USAISR included a letter of endorsement from the President of the ABA.
- b. Once information was received from (a) above, the USAISR put together an Access database that:
 1. Each morning (0600 Central Standard Time (CST)), queried, at one time, all the participating sites on their bed availability with one email. Participating Burn Units needed to report no later than (NLT) 1000 CST with their burn bed situation.
 2. Data was uploaded to the Access database as it came in.
- c. By 1200 CST, USAISR provided a list of the available U.S. burn beds by Burn Center for that day to the Armed Services Medical Regulator Office (ASMRO) at Landstuhl Army Medical Center/Ramstein Air Force Base (AFB). If the casualty numbers had been what was estimated and the facilities at the USAISR were maxed out, the ASMRO could then direct the evacuation flights to a Burn Center near the casualty's home of record.
- d. Did it work? Yes, it was built for the military evacuation system in cooperation with civilian medical facilities and it worked to the point of actually transferring patients to civilian Burn Centers. It was a success because it was endorsed by the ABA, U.S. Burn Centers were willing to be a part of it, a USAISR burn surgeon at Landstuhl was a key contributor, and it was devised and managed by the USAISR.

It is the goal of the proposed effort to streamline the transfer and management process using the latest technology, such as a mobile “app” (as well as web-browser based access) to input burn and trauma bed status/ availability for the ABA-verified Burn Centers and Level 3 and 4 Trauma centers, and automatically upload into a cloud-based database available to an ASMRO- like individual acting as the central military transportation clearing authority, as well as other stakeholders, such as the participating Burn Centers/Trauma Centers/Department of Homeland Security/National Disaster Management System, local/state/national Emergency Medical Services (EMS) Coordinating system(s) and NATO Partner Nations.

Some additional considerations in regards to the proposed effort are:

- how to best integrate with civilian on-scene incident personnel/first responders who are the key decision-makers for patient transport in civilian disasters/emergency response efforts as well as Department of Homeland Security National Disaster Management Systems.
- best way to deal with interstate transfer agreements and liability protection(s) in order to make disaster preparedness efforts easier for both military and civilian systems – including federal, state, and local jurisdictional, policy, and legal considerations
- operations/integration under varied communications modes, such as, but not necessarily to include internet, cellular, first responder radio and interoperability requirements across transmission facilities and equipment
- how to add ad-hoc/on-demand participation from other hospitals or clinics that have unanticipated patients in the community arriving at their doorstep and need to refer to one of the specialty designated burn/trauma centers in the network
- Department of Homeland Security and NATO Partner Nations' capabilities for global/regional civilian and military disasters per Phase 3

4.2.2 Specific Aims of RPP

The Military Health System (MHS) seeks to leverage best practices and emerging technologies/trends by partnering with a broad array of already-engaged and leading edge industry and academic experts in the identification, development, testing and research of leading edge, open source data and tools that will:

- increase agility in delivering current and future capabilities both to the military and for U.S. civilian disaster management for determining burn/trauma bed/treatment availability on-demand, and for proactive, predictive, future capacity planning purposes;
- employ industry open-source tools and best practices including approaches that leverage open source software and other standards-based, non-proprietary interoperable capabilities to create an agile, mobile, easy to use, intuitively operated system/app;
- capitalize upon best practices and lessons learned by Government, industry, and academia;
- attract and engage experts in a team approach to improve military burn/trauma care management for bed assignments and practices;
- maximize and apply innovation to Defense Burn/Trauma response; and
- demonstrate opportunities for enhanced support and greater reliability and efficiency at every stage of the medical transfer process for burn/trauma casualties.

The working prototype developed as a result of this effort would provide the architecture, demonstrate and deliver to the government a proof of concept, and prepare technical development documents that leverage industry best practices and solutions for integration within the existing Defense Health Agency (DHA)/MHS in peace time and wartime, in a two-phased approach. This includes identifying, demonstrating and developing a roadmap of planning and requirements definition. Elements of the prototype could include a model of a highly scalable, industry/open standards-based infrastructure, and new technology applications providing highly reliable, high-integrity capabilities on a nationwide basis. Support for the various end-user communities within segmented, authorized and authenticated communities of interest with specific subsets of business transaction processes within the system would be highly desired.

One embodiment of the reference model and prototype implementation could include the concept of proactive business intelligence and capacity planning/forecasting, and patient tracking within multiple federated MHS internal and external domains, networks, and stakeholders/partners. The solution could demonstrate feasibility and approach for business transformation across all aspects of disaster management as well as the underlying supporting architecture and model(s) encompassing core functional and data management processes including registration processes and ongoing configuration, data management and administration of the communities of interest and their business objects along with logging/monitoring functions. Further, integration with the TRANSCOM Patient Movement procedures and IT system (i.e., TRACES2 under development), and civilian EMS/ National Disaster Medical System (NDMS), and other identified systems in the MHS/DHHS will be considered an essential component of the reference model and prototype. Most notably, new elements of high interest and value and that also will need to interoperate seamlessly with existing infrastructure that could be used on a day-to-day basis for routine EMS/Burn/Trauma transports, as well as in Civilian/Military disaster or mass casualty events.

4.2.3 Research Plan

The research is expected to be conducted in three phases over a 3 year period of time as follows:

Phase 1 – 6 to 9 months

The specific aims of Phase 1 are:

- 1) to conduct a comparative study of similar/existing commercial data management tools and capabilities and relevant clinical capacity/resourcing applications, and
- 2) conduct a requirements definition process that supports the development of the Burn Patient Transfer System (BPTS).

The Phase 1 research will include the investigation of similar private/public industry software solutions with similar operational baselines, to determine how other initiatives with similar

functionality/capability operate. Similarly, innovative trends and methods being developed in industry and academia will be investigated. This work should explore how industry leaders would utilize a mobile app and web browser accessible cloud-based system and what data and processes need to be tracked and coordinated across diverse military and civilian stakeholders/partners to deliver a seamless capability to the user with definitive medical planning capabilities for real-time situational awareness. The performer will be asked to examine both civilian and Defense Medical Systems for patient transport, patient tracking, and bed management in the event of a disaster.

Research questions for Phase 1 include, but are not limited to:

- 1) How does industry utilize, structure, and synthesize authoritative data from multiple sources in meaningful views to support improved decision-making at all levels of management and care?
- 2) Is industry enabling higher functioning reporting capabilities through strategic use of electronic health records and innovative, next generation business intelligence reporting including of just-in-time status of medical/clinical assets, real-time location tracking, positioning and placement reservations, and other novel methods that can be leveraged successfully to achieve the objectives of the BPTS? How do the reporting capabilities increase patient safety and reduce time to operational readiness? What exists in industry solutions that can be repurposed for the system?
- 3) How well does the approach compare to industry for the delivery of a simplified enterprise dashboard that allows senior leaders and multiple stakeholders to view standardized metrics on the BPTS real-time status?
- 4) What data analytics and reporting tools exist that can promote a proactive, informed user response to decisions?
- 5) What are the different data elements and item attributes needed to enable rapid patient transfer/patient movement decisions?
- 6) What are the system interfaces that enable participants in the BPTS to exchange information easily and intuitively at any experience level? What technology solutions and best practices are being successfully employed by other large enterprises? What are the differences in the industry solution(s) technology stack(s) that enable the potential for higher functionality with Cerner electronic health records (EHR)?
- 7) What proprietary networks, if any, within fire/EMS/NDMS/ DoD/Federal, as well as state and local levels must the system be able to operate on and maintain interoperability with, or is all command and control supported through a secure-cloud-based ubiquitous computing and access management virtualized environment using industry standard cloud services/mobile app authentication, authorization and access capabilities?
- 8) How are PHI handled in other systems related to the needs for BPTS?

Phase 2 – 15- 18 months

The specific aim of Phase 2 is to develop a working prototype/model application of an open-source, mobile, Android (primary platform for DoD use)/ iOS app and cloudbased BPTS. The prototype will demonstrate utilization of explored and determined feasible industry technologies and best practices, integrated with the military civilian EMS state and local systems to establish the feasibility of the approach and demonstrate a system for combined military/civilian burn care capacity. The system will deliver the capability to identify, and utilize available data, logistics, data structures, and tools to improve decision-making, and to improve timeliness to definitive burn/trauma care throughout the entire length of the initial injury to arrival at definitive treatment facility. The prototype should be focused on the integration of available technologies including, but not limited to, easy user interface, intuitive operations requiring no or minimal training, open architecture, required algorithms, data structures, analytics tools, and necessary reporting.

Phase 2 should apply the findings of Phase 1, i.e., best industry practices, tools, and strategies to the medical planning/capacity model/prototype for the BPTS and produce a modern streamlined real-time/near-real time system prototype that demonstrates the use of 'running code', caveating operational differences; placing attention on solutions to reconcile varying information arriving from many sources (participating facilities and providers, as well as ad-hoc community hospitals, clinics with demand, etc.) from disparate sources into one environment that can be presented to a user (first responder, planner, management, etc.) according to geographic regions (to be determined during the local, state and federal user requirements gathering process).

Phase 2 should research the usability (assessing desired minimum to no user training requirement), efficiency and efficacy of the proposed prototype system with representative users in order to develop iterative improved prototype versions, to culminate in an advanced prototype final deliverable.

Research questions for Phase 2 include, but are not limited to:

- 1) How will BPTS utilize and structure authoritative data from multiple sources to support improved decision-making at all levels of military/civilian burn/trauma management and care?
- 2) How will BPTS enable higher functioning, next generation business intelligence and decision support reporting capabilities? How will the reporting capabilities increase patient safety and reduce time to definitive burn/trauma care delivery? What automation can exist in BPTS that will enable maturity reporting?
- 3) What BPTS technologies are required for the delivery of a simplified enterprise dashboard that allows senior leaders and decision-makers to incorporate and/or view

standardized metrics on capacity, for medical planning, and triage and referral in real-time?

- 4) What data analytics and reporting tools can exist in BPTS that can promote a proactive, informed user response to burn/trauma treatment decisions?
- 5) How will BPTS exchange the different data elements and item attributes that are utilized in industry to build and maintain requisite the data elements, a data dictionary of meta-data, catalogs and thesauruses for both syntactic and semantic exchange between systems and participant facilities, providers and other users that enable rapid patient transfer decisions?
- 6) What system interfaces will BPTS require to exchange information so that information is intuitive to users at any experience level? What tools will enable the integration and use of open standards and secure computing to enable the greatest level of interoperability across facilities, federal, state and local actors utilizing the BPTS?
- 7) What BPTS capabilities will exist in the model that enables the potential for higher functionality, i.e., integration with health data exchange/TRANSCOM TRACES2/other IT systems across multiple facilities including interoperability using industry standards for medical record documentation and exchange?

Phase 3 – 12 months

Phase 3 will focus on testing/usability and integration of the demonstrated system features and functionality developed in the previous Phases into U.S. Department of Homeland Security (DHS)/National Disaster Management System (NDMS) federal response/incident management at the federal level as well as NATO Partner Nations. Phase III expands the BPTS across NATO Partner Nations' military and US federal sectors for situational awareness to increase capacity in large-scale disaster/casualty response scenarios on a global basis. The offeror will be expected to work with DHS and NATO points of contact in this future expansion phase to determine integration requirements and implement the specified functionality. The Government will facilitate introductions to DHS and NATO POC's for this phase.

4.2.4 Requirements

DoD Instruction (DoDI) 6000.11, "Patient Movement" establishes United States Transportation Command (USTRANSCOM) as the Department of Defense (DoD) single manager for Global Patient Movement as the global functional manager for maintaining, operating, and identifying requirements for Automated Information Systems (AIS). While the BPTS will be used for both military and civilian burn injury medical capacity referral, the USTRANSCOM can provide guidance on the types of functionality needed for a combined BPTS supporting both sets of medical needs.

In a JROC Memo dated 28 Feb 2017, Theater Medical Information Requirements (TMIR) Information System (IS)-CDD documents the knowledge management capabilities required to enable the following operational health care functions including Medical Command and Control (Med.C2); Medical Situational Awareness (MedSA); and Patient Movement (PM). Specifically the requirement for the development and functional availability for a key performance parameter to have authorized users available to document medical care and prepare patient movement requests and conduct medical planning.

The Joint Operational Medicine Information Systems (JOMIS) PM Requirements Definition Package (RDP) (Version 1.5) cites the following key requirements, including but not limited to:

- Safe, effective, and efficient patient movement requires considerable planning and coordination across multiple organizations throughout the process, including but not limited to:
- Submission, collection, and prioritization of requests for patient movement
- Longitudinal documentation of the medical condition of and the care rendered to a patient
- Timely communication of clinical records to the next level of care and medical validation authorities
- Medical regulating to ensure patients are distributed to staging and destination medical treatment facilities that have the capability and capacity to provide needed care
- Clinical validation that patients require and are medically ready for evacuation and the documentation of movement restrictions
- Identification of medical equipment and supplies required for patient care, including Patient Movement Items (PMI) and expendable supplies (e.g. meals, bandages, etc.)
- Verification of PMI compatibility with the selected mode(s) of transportation
- Replenishment of PMI
- Communication of prioritized patient movement requirements to lift and en route care organizations and the assignment of resources
- Documentation and dissemination of patient movement plans
- Reporting the status and location of patients and PMI during PM execution

4.2.5 Project Deliverables

The end result of the proposed work is expected to be an advanced prototype with “running code” for the BPTS, as an innovative, open source, mobile-based, dual-Android/ iOS on the device side (as well as browser accessible) application using secure, DoD Compliant virtualized, cloud-based services (RESTful or SOA or other modern architectures) for the back-end database

and server applications infrastructure. The prototype would include the architecture, a working advanced prototype system with running/operational code at a level of maturity, the features and functionality of which has been demonstrated and validated with first responders, burn center hospital personnel and disaster management personnel at the federal level. In addition, the deliverables include technical development documents that leverage industry best practices and solutions for integration within the existing Defense patient movement/NMDS/ framework to improve precision by system analysts and end users. Deliverables will include, but not limited to prototype user interfaces, modified Data and Information Viewpoints (DIV-1, DIV-2, and DIV-3), modified All Viewpoints (AV-1), (AV-2), modified BPTS Capability Viewpoints, modified BPTS System Viewpoints, and modified BPTS Operational Viewpoints. The prototype as well as all electronic project artifacts including source code, executables, data files, meta-data (including the data dictionary) will be delivered at the end of the project to a DoD-specified code and data repository. The DoDAF-described Models will demonstrate utilization of explored industry technologies and best practices, integrated within BPTS to deliver the ability to identify, expose, and utilize available data, logistics, algorithms, data structures, and analytics tools to improve patient transfer decision-making, to improve time to definitive burn/trauma care. The model should be focused on the integration of available and emerging technologies including architecture changes, algorithms, data structures, and analytics tools within BPTS.

It is anticipated that the prototype work products including electronic project deliverables including but not limited to requirements, design documents, specifications, data, meta-data, source code and compiled execution files will be the property of the U.S. government. All deliverables will be posted to an industry/open source standard secure data/software repository with appropriate version control in a format specified by the government for use in emergency response and disaster management applications.

4.2.6 Collaboration Points:

The proposers will need to plan for interface and collaboration in their proposal with both USAISR and the TRANSCOM.

Both US Army Institute for Surgical Research and TRANSCOM will be separately funded to each provide approximately .25 FTE of military/medical subject matter expertise. This would include consulting support such as clinical/technical guidance as needed, input/ review of the requirements during the requirements definition process and review/comment on design documentation and test results from the performer during prototype design and development of the BPTS system. The Government will provide POC's for ISR and TRANSCOM at time of award.

4.3 Preparation of the Proposal

The Technical Proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (19-01-BPTS). The Technical Proposal and Cost Proposal must be submitted in

two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following:

- **Technical Proposal submission:** one signed Technical Proposal (.pdf, .doc or .docx). The Technical Proposal must follow the format provided in the PPG.
- **Statement of Work/Milestone Payment Schedule:** one Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Attachment A). The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.
- **Cost Proposal by Task submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required. Separately, Section II: Cost Proposal **by Task** Formats in Excel (.xlsx or .xls) is required.
- **Warranties and Representations:** one Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee **or** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

Evaluation: The Government will evaluate and determine which proposals to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4 Cost Proposal

Offerors are encouraged to use their own cost formats such that the necessary detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost by Task Proposal formats provided in the MTEC PPG are **NOT** mandatory. Refer to the MTEC PPG for additional details.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

4.5 Proposal Preparation Costs

The cost of preparing Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4.6 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Proposals must comply (as applicable) with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying MTEC PPG, "Additional Requirements."

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

For example, the clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

5 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. Proposals that do not meet these requirements may be eliminated from the competition or additional information may be requested. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see RPP Section 2.8). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

| TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS | |
|---|--|
| RATING | DESCRIPTION |
| PASS | Offeror proposing an MTEC research project meets at least ONE of the following: <ul style="list-style-type: none">• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution |

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| | |
|------|--|
| | <ul style="list-style-type: none"> • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share |
| FAIL | <p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share |

Following the preliminary screening, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. *Select the proposal (or some portion of the proposal) for award*
2. *Place the proposal in the Basket if funding currently is unavailable; or*
3. *Reject the proposal (will not be placed in the Basket)*

5.1 Proposal Evaluation Process

Qualified applications will be evaluated by a panel of subject matter experts who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 2.3.

Evaluation of proposals shall be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The evaluation factors and evaluation criteria are described below.

5.2 Evaluation Factors

1. Technical Approach

2. Potential for Transition and Commercialization
3. Cost/Price

Evaluation factors are listed in descending order of importance with the weighting percentage in parenthesis. The Technical Approach factor and Cost/Price Cost/Price factor are significantly more important than the Potential for Transition and Commercialization factor, when combined; however, Potential for Transition and Commercialization will contribute to the selection decision. As the collective non-transition and commercialization factors begin to reach equality in the technical evaluation and cost ratings, transition and commercialization becomes a more important factor in the trade off analysis.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

| TABLE 2- GENERAL MERIT RATING ASSESSMENTS | |
|--|---|
| RATING | DESCRIPTION |
| OUTSTANDING | Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low. |
| GOOD | Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low. |
| ACCEPTABLE | Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate. |
| MARGINAL | Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high. |
| UNACCEPTABLE | Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable. |

5.2.1 Evaluation Factor 1. Technical Approach

The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in Section 5.2 above. The likelihood of

success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and the suitability of the proposed statistical plan. The SOW should provide a succinct approach for achieving the project's objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable advances the TRL Military relevance is a critical component of proposal submission. This relevance includes the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution. A description of the project team's expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

5.2.2 Evaluation factor 2: Potential for Transition and Commercialization

The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

- a) How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
- b) How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
- c) How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- d) How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
- e) How well the regulatory strategy is described, if applicable.

5.2.3 Evaluation Factor 3. Cost/Price

The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

assessment and make the final determination that the negotiated project value is fair and reasonable.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

c) Completeness. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

5.3 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Approach Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4 Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

6 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, Ms. Rebecca Harmon, mtec-contracts@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org. or Mr. William Howell, Chief Operating Officer, William.howell@tunnellgov.com.

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director, execdirect@officer.mtec-sc.org.
- All other questions should be directed to Ms. Kathy Zolman, MTEC Program Manager, kathy.zolman@ati.org

Once an Offeror has submitted a Proposal the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

7 Acronyms/Abbreviations

| | |
|-------|--|
| ABA | American Burn Association |
| AFB | Air Force Base |
| AIS | Automated Information System |
| ASMRO | Armed services Medical Regulator Office |
| ATI | Advanced Technology International |
| AV | All Viewpoints |
| BPTS | Burn Patient Transfer System |
| CAS | Contract Accounting System |
| CDD | Capabilities Development Document |
| CM | Consortium Manager |
| CMA | Consortium Member Agreement |
| CST | Central Standard Time |
| DHS | Department of Homeland Security |
| DIV | Data and Information Viewpoint |
| DoDAF | Department of Defense Architecture Framework |
| DoDI | Department of Defense Instruction |
| DUNS | Dunns and Bradstreet Number System |
| EHR | Electronic Health Record |
| EMS | Emergency Medical Services |
| FAQ | Frequently Asked Questions |
| F&A | Facilities and Administrative Costs |
| FEMA | Federal Emergency Management Agency |
| FHIR | Fast Healthcare Interoperability Resources |
| FY | Fiscal Year |
| G&A | General and Administrative Expenses |
| ICU | Intensive Care Unit |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| IR&D | Independent Research and Development |
| IT | Information Technology |
| JOMIS | Joint Operational Medical Information System |
| JROC | Joint Requirements Operations Capability |
| JPC-1 | Joint Planning Committee-1 |
| MedC2 | Medical Command and Control |
| MedSA | Medical Situational Awareness |
| MHS | Military Health System |
| MTEC | Medical Technology Enterprise Consortium |
| M | Millions |
| MSIS | Medical Simulations and Information Systems |

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| | |
|----------|---|
| MSISRP | Medical Simulation and Information Sciences Research Program |
| NATO | North Atlantic Treaty Organization |
| NDA | Nondisclosure Agreement |
| NDMS | National Disaster Medical System |
| OCI | Organizational Conflict of Interest |
| ODC | Other Direct Charges |
| OIF/OEF | Operation Iraqi Freedom/Operation Enduring Freedom |
| ORP | Office of Research Protections, USAMRMC |
| OTA | Other Transaction Agreement |
| pOTA | Prototype Other Transaction Agreement |
| PDF | Portable Data File |
| PM | Patient Movement |
| PMI | Patient Movement Item |
| POC | Point-of-Contact |
| PPG | Proposal Preparation Guide |
| R&D | Research and Development |
| RDP | Requirements Definition Package |
| RPP | Request for Project Proposals |
| SME | Subject Matter Expert |
| SOW | Statement of Work |
| TMIR | Theater Medical Information Requirement |
| TRACES2 | TRANSCOM Regulating and Command and Control Evacuation System (2) |
| TRANSCOM | Transportation Command |
| TRL | Technology Readiness Level |
| USAMRMC | U.S. Army Medical Research and Materiel Command |
| USAISR | U.S. Army Institute of Surgical Research |
| USG | U.S. Government |
| VA | Veteran's Administration |

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

Introduction/Background (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.*)

Scope/Project Objective (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.*)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

Requirements (*To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective*).

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

Deliverables *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all electronic deliverables such as hardware/software to be provided to the Government as a result of this project shall be identified. Written deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Example

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| MTEC Milestone Number | Task Number | Significant Event/ Accomplishments | Due Date | Government Funds | Cost Share | Total Funding |
|-----------------------|-------------|--|------------|------------------|---------------|---------------|
| 1 | N/A | Project Kickoff | 12/1/2019 | \$20,000 | | \$20,000 |
| 2 | N/A | Quarterly Report 1 (October - December, Technical and Business Reports) | 1/25/2020 | \$ - | | \$ - |
| 3 | 1 | Protocol Synopsis | 2/28/2020 | \$21,075 | | \$21,075 |
| 4 | 2 | Submission for HRPO Approval | 2/28/2020 | \$21,075 | | \$21,075 |
| 5 | 3 | Submission of Investigational New Drug application to the US FDA | 4/30/2020 | \$210,757 | \$187,457 | \$398,214 |
| 6 | N/A | Quarterly Reports 2 (January - March, Technical and Business Reports) | 4/25/2020 | \$ - | | \$ - |
| 7 | N/A | Quarterly Report 3 (April - June, Technical and Business Reports) | 7/25/2020 | \$ - | | \$ - |
| 8 | 4 | Toxicity Studies | 10/1/2020 | \$63,227 | | \$63,227 |
| 9 | N/A | Annual Report 1 | 10/25/2020 | \$ - | | \$ - |
| 10 | 5 | FDA authorization trial | 11/30/2020 | \$84,303 | | \$84,303 |
| 11 | 6 | Research staff trained | 11/30/2020 | \$ - | | \$ - |
| 12 | 7 | Data Management system completed | 11/30/2020 | \$ - | | \$ - |
| 13 | 8 | 1 st subject screened, randomized and enrolled in study | 1/1/2021 | \$150,000 | \$187,457 | \$337,457 |
| 14 | N/A | Quarterly Report 4 (October - December, Technical and Business Reports) | 1/25/2021 | \$ - | | \$ - |
| 15 | 9 | Completion of dip molding apparatus | 3/1/2021 | \$ 157,829 | \$ 187,457 | \$ 345,286 |
| 16 | N/A | Quarterly Reports 5 (January - March, | 4/25/2021 | \$ - | | \$ - |

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| | | | | | | |
|----|-----|---|--------------|--------------------|--------------------|--------------------|
| | | Technical and Business Reports) | | | | |
| 17 | 10 | Assess potential toxicology | 6/1/2021 | \$157,829 | | \$157,829 |
| 18 | N/A | Quarterly Report 6 (April - June, Technical and Business Reports) | 7/25/2021 | \$ - | | \$ - |
| 19 | 11 | Complete 50% patient enrollment | 10/1/2021 | \$350,000 | \$187,457 | \$537,457 |
| 20 | N/A | Annual Report 1 | 10/25/2021 | \$ - | | \$ - |
| 21 | N/A | Quarterly Report 7 (October - December, Technical and Business Reports) | 1/25/2022 | \$ - | | \$ - |
| 22 | 12 | Electronic Report Forms Developed | 3/1/2022 | \$315,658 | \$187,457 | \$503,115 |
| 23 | N/A | Quarterly Reports 8 (January - March, Technical and Business Reports) | 4/25/2022 | \$ - | | \$ - |
| 24 | N/A | Quarterly Report 9 (April - June, Technical and Business Reports) | 7/25/2022 | \$ - | | \$ - |
| 25 | 13 | Complete 100% patient enrollment | 8/1/2022 | \$315,658 | \$187,457 | \$503,115 |
| 26 | N/A | Annual Report 1 | 10/25/2022 | \$ - | | \$ - |
| 27 | 14 | Report results from data analysis | 11/1/2022 | \$157,829 | | \$157,829 |
| 28 | N/A | Final Reports (<u>Prior to the POP End</u>) | 11/30/2022 | \$ - | | \$ - |
| | | | Total | \$2,025,240 | \$1,124,742 | \$3,149,982 |

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.
3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in subcontract.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

Shipping Provisions *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:
Classified Shipments:
Outer Packaging
Inner Packaging

Data Rights *(see Section 8.4 of PPG for more information)*

| Technical Data or Computer Software to be Furnished with Restrictions | Basis for Assertion | Asserted Rights Category | Name of Organization Asserting Restrictions | Milestone # Affected |
|---|---|---------------------------|---|------------------------|
| Software XYZ | Previously developed software funded exclusively at private expense | Restricted | Organization XYZ | Milestones 1, 3, and 6 |
| Technical Data Description | Previously developed exclusively at private expense | Limited | Organization XYZ | Milestone 2 |
| Technical Data Description | Previously developed with mixed funding | Government Purpose Rights | Organization XYZ | Milestone 2 |

Reporting *(The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)*

Request for Project Proposals MTEC-19-01-BPTS
Number W81XWH-15-9-0001

| Report Months | Due Date |
|----------------------|-----------------|
| January – March | 25 April |
| April - June | 25 July |
| July - September | 25 October |
| October - December | 25 January |

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)