Request for Project Proposals

Solicitation Number: MTEC 19-09-TheaterBlood

"Mobile Application Development Proof of Concept - Theater Blood"

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: July 1, 2019

Proposal Due Date: August 7, 2019
Noon Eastern Time

<u>*White Papers Are NOT Required*</u>

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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 this 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 Department of Defense (DoD), Program Executive Office (PEO) Defense Healthcare Management Systems (DHMS), Joint Operational Medicine Information Systems (JOMIS) Program Office (PMO), in partnership with the Defense Health Agency (DHA), Contracting Division - Defense Healthcare Management Systems (CD-DHMS). Military relevance is a critical component of the Proposal submission. Strategic oversight for the award(s) supported by this RPP will be provided by the Program Executive Officer, PEO DHMS. The collective DHMS organizations consider this an "Execution" procurement action to fulfill a portion of the JOMIS prime mission to modernize elements of Medical Command and Control (MedC2), Medical Situational Awareness (MedSA), Medical Logistics (MEDLOG), and Health Care Delivery (HCD) operational medicine healthcare functions.

The goal of this project is to develop a prototype capability that provides military personnel deployed in theater the ability to manage and document blood inventory, transfusions, blood product donations, and transfusion transmittable disease (TTD) testing in environments that may

be disconnected, have intermittent connectivity, or have low-bandwidth connections to the network and synchronize that data with the enterprise database when connectivity is available. To facilitate the development effort, JOMIS will provide the Operational Medicine Mobile (OMM) Collaborative Development Environment (CDE), including associated tools and processes, and the OMM Collaborative Development Framework (CDF) to develop and demonstrate a prototype disconnected application for Theater Blood that meets functional requirements (see Section 5 of RPP for Government Furnished Information). A secondary purpose of this prototyping effort is to obtain feedback on the JOMIS CDE and CDF and recommendations for its maturity and improvement.

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 Proposers Conference
MTEC will host a Proposers Conference that will be conducted via webinar within the first two weeks after the release of the RPP. Further instructions will be forthcoming via email.

2.3 Funding Availability, Period of Performance, and Type of Funding Instrument Issued

The U.S. Department of Defense (DoD) currently has available approximately $1.5 – 3.0 Million (M) Defense Health Program (DHP) Research, Development, Test and Engineering (RDT&E) to support this effort (Tasks 1 and 2). The U.S. Government (USG) may apply additional dollars for follow-on efforts with appropriate modification after the evaluation and acceptance of work and cost plan.

The Period of Performance (PoP) is up to 12 months to complete Tasks 1 and 2, which are described below. Dependent on the results and deliverables from Tasks 1 and 2, additional time may be added to the period of performance for follow-on tasks.

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. Award funding will be structured incrementally and based upon completion of milestones.

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 website and 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.

2.4 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 organizations. 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.

2.5 Offeror Eligibility
Offerors must be MTEC Members in good standing.

2.6 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. Please see the MTEC PPG and RPP (Section 6) for additional details.

2.7 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.

2.8 Requirements
If the Offeror asserts either:

(1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

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

2.9 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.

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.

2.10 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.

2.11 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.

2.12 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 unless otherwise asserted in the proposal and agreed to by the Government.** 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
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

2.13 Expected Award Date
Offeror should plan on the period of performance beginning November 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.

2.15 Organizational Conflicts of Interest

This solicitation contemplates work that could result in organizational conflicts of interest with ongoing or future work supporting the Program Executive Office - Defense Healthcare Management Systems or other Department of Defense Programs.

In particular, this solicitation will likely result in the provision of systems engineering services, preparation of technical specifications, and access to other contractor's proprietary information relative to, but not necessarily limited to the following programs:

- TMIP-J
- JOMIS
- Defense Medical Information Exchange (DMIX)
- DoD Healthcare Management System Modernization (DHMSM)

Any resulting award will require the awardee to notify the cognizant contracting offices (e.g., CD-DHMS) if any member of the team: prime, subcontractor, vendor, consultant, joint venture, etc. has performed work under an award resulting from this solicitation, if any of the entities intends to bid on other related solicitations. Future related solicitations will also require this notification as a matter of compliance.

Further, awardees may be required to execute non-disclosure, non-compete, or business associate agreements as required.

3   Proposal

3.1   Proposal

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 may not be evaluated.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format outlined in the 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 **August 2, 2019**.

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-19-09-TheaterBlood). 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

Program Description:
JOMIS is responsible for developing, deploying, sustaining and modernizing operational medicine IT systems that support the delivery of comprehensive health services to deployed forces across the full range of military operations. The operational medicine functional areas JOMIS supports are Medical Command and Control (MedC2), Medical Situational Awareness (MedSA), Medical Logistics (MEDLOG), Health Care Delivery (HCD), and Patient Movement (PM). The current suite of operational medicine IT systems supporting deployed forces is the Theater Medical Information Program – Joint (TMIP-J), which includes the current DoD Theater Blood (TBLD) capability. The Theater Blood mission supports, or is supported by elements of the HCD, MedSA, MEDLOG and MedC2 operational medicine healthcare functions.

The Armed Services Blood Program, through the joint efforts of the Army, Navy and Air Force, collects, processes and ships blood and blood products to members of the U.S. Armed Forces across the globe to ensure viable blood products are available for transfusion when and where required, including dynamic operational environments ranging from austere land and sea operations to fixed locations in a mature operational theater.

Technical Background:
Theater Blood operations are currently supported by the TMIP-J enterprise Theater Medical Data Store (TMDS) application. Users must access current TMDS Theater Blood capabilities via a web browser to perform a variety of functions focused on ensuring the integrity of the supply chain and quality of blood products. These blood support functions are closely coupled with clinical services to ensure the total life cycle tracking of blood products from the point of origin/donor ultimately to the transfused patient or point of destruction. In the operational environment, however, the blood community often works in medical support facilities that are either disconnected, have intermittent connectivity, or low-bandwidth connectivity (DIL) to DoD enterprise networks. Thus, there is a requirement for a solution that allows for the management and capture of Theater Blood data in an offline mode, and for the synchronization of data captured in the offline mode with other local users and eventually with the enterprise Theater Blood application when connectivity to the enterprise becomes available. Because the Theater Blood solution is used outside the United States, it is not subject to certification by the Food and Drug Administration (FDA).

The goal of this project is to support RDT&E activities required to develop prototype mobile applications that will extend current Theater Blood capabilities to users working in the DIL environment and allow them to continue to perform local business processes and functions required to ensure the integrity of the supply chain management and quality of blood products

while disconnected from the network. This includes being able to view, modify, and update blood product inventory; identify and screen donors and accept donations; document TTD testing results and transfusion of blood products while disconnected, and synchronize the data with other local devices and with the enterprise Theater Blood application when connectivity to the enterprise becomes available.

Theater Blood users require the capability to access and utilize JOMIS services on whatever device they are issued. Configurations requiring offline support range from a single local user with a single computing platform, to several local users with multiple computing platforms. Currently, the projected target platforms for the Theater Blood prototype are Windows operating system laptops and desktops and DISA approved Android and iOS devices.

In order to minimize the level of effort required to develop and maintain cross-platform mobile services, and realize efficiencies through code reuse across JOMIS services, JOMIS established the Operational Medicine Mobile (OMM) Collaborative Development Environment (CDE) and Collaborative Development Framework (CDF). JOMIS uses Defense Information Systems Agency's (DISA's) ProjectForge to host the OMM CDE. The CDF contains a software developers kit (SDK) that consists of componentized functionality in the form of C# class libraries, and a service layer that contains a set of application programming interfaces (APIs) by which the componentized functionality contained in the C# class libraries can be utilized by other mobile apps. The CDF also contains a set of shared services applications which augment the SDK. These shared service applications currently consist of:

- A Single Sign-On application which manages Authentication and Authorization functions for all users of OpMed Mobile applications
- A Patients application that provides patient demographics info to those OpMed mobile apps that require this information
- A Transport app that provides a data communications capability between back office systems and OpMed mobile apps that require this capability

Guiding technical principles used to create the componentized functionality contained in the SDK, and to be used for the architectural construction of applications that will be built within the JOMIS OMM CDE, are contained within Chapter 1, Paragraph 1, pages 1-10, of the DoD Open Systems Architecture Contracting Guidebook for Program Managers, June 2013. According to the ExSum of this document, "The essence of Open Systems Architecture (OSA) is organized decomposition, using carefully defined execution boundaries, layered onto a framework of software and hardware shared services and a vibrant business model that facilitates competition. OSA is composed of five fundamental principles:

1. Modular designs based on standards, with loose coupling and high cohesion, that allow for independent acquisition of system components.
2. Enterprise investment strategies, based on collaboration and trust, that maximize reuse of proven hardware system designs and ensure we spend the least to get the best.

3. Transformation of the life cycle sustainment strategies for software intensive systems through proven technology insertion and software product upgrade techniques.
4. Dramatically lower development risk through transparency of system designs, continuous design disclosure, and Government, academia, and industry peer reviews.
5. Strategic use of data rights to ensure a level competitive playing field and access to alternative solutions and sources, across the life cycle."

The CDF capabilities, and how to use them to construct applications that can be compiled to run on both android and iOS mobile platforms, are documented in the OpMed Mobile Cookbook, the OpMed Mobile Service Layer User Guide (SLUG), and specific documentation for the shared services applications (provided for potential Offerors on the members-only website). The OpMed Mobile CDF elements, the associated source code and documentation are hosted on the JOMIS OMM CDE forge.mil page.

Access to the OMM CDE and CDF will be provided to the Awardee(s) who have executed necessary controlled cryptographic material protection and non-disclosure agreements to support development and code re-use across solutions developed to meet JOMIS requirements (see Section 5 of the RPP). Offerors may provide recommendations to change, modify, or amend the JOMIS OMM CDE/CDF or provide alternative approaches with supporting rationale. The Awardee will be required to provide feedback and recommendations to mature the processes, activities, and capabilities of the JOMIS OMM CDE and CDF.

Project Deliverables:
To support the preparation of proposals, JOMIS has provided potential Offerors with source code and video demonstrations of a previously developed theater blood mobile application, and a high level set of approved requirements in various formats (see Section 5 of the RPP). Following award, the selected Awardee(s) will facilitate user story development, and will be provided access to the JOMIS OMM CDE to support the development of the new prototype capabilities. The Awardee will conduct a Preliminary Design Review (PDR) in the form of a briefing to depict the preliminary design based on initial interpretation of the Government's requirement. The Awardee will also conduct a Critical Design Review (CDR) to depict any updates to design based on guidance received from the Government in the PDR. In addition to providing the Government a working prototype application that meets functional requirements, at the end of each task the Awardee(s) shall provide lessons learned from experiences working with the OMM CDE and CDF in the form of a report back to JOMIS. The Awardee(s) will also assist the Government with demonstration of the new prototype capabilities in locations specified by JOMIS, and assist the Government with planning for transition of the new prototype to an accredited production quality application. The Government expects to receive the following deliverables with accompanying DD250:
- Software source code at each software delivery (via CDE)
- Compiled executables/VMs/Containers at each software delivery (via CDE)
- Software Sustainability Package (SSP) at each software delivery

- Software Requirements Specification (SRS) draft to support PDR, updated to support CDR, updated with each software delivery as necessary
- Software Design Description (SDD) draft to support PDR, updated to support CDR, updated with each software delivery as necessary
- Software Development Plan (SDP) draft to support PDR, updated to support CDR, updated with each software delivery as necessary
- Software Version Description (SVD) with each software delivery
- Software Compilation and Installation Instructions/Build Automation Scripts at each software delivery (via CDE)
- Software User Manual (SUM) updated with each software delivery
- Software Test Plan (STP) with each software delivery/Test Case Scripts at each software delivery (via CDE)
- Software Test Report (STR) with each software delivery
- Software Test Description (STD) to accompany each STP and STR
- Information Security Self-Assessment Report prior to the end of the PoP
- OMM CDE/CDF Lessons Learned Report at the end of each task
- Tools test harnesses

The content of these deliverables is expected to be tailored to contain only necessary and relevant data in accordance with Agile principles regarding just enough documentation. Offerors may recommend the combination, elimination, or addition of documentation in accordance with their technical and programmatic approach. Format may be negotiated with the Government.

The full spectrum of work is expected to be conducted in two tasks within a 12 month PoP, as follows:

Task 1:
Develop a mobile application prototype that focuses on **one** of the following three capability areas: Inventory Management, Donor Management, or Transfusion Management. The functional prototype developed under Task 1 must meet the following requirements (subject to change):

- Must demonstrate the ability to meet Theater Blood capabilities documented in Government Furnished Information (GFI) 14 *TBLD IS Capabilities Table*, consistent with the legacy prototype Theater Blood mobile application provided to Offerors as GFI
- Must be fully compliant with DoD Modular Open Systems Architecture requirements
- Must be delivered within the OMM CDE
- Must be developed using Agile Scrum methodology
- Must be integrated, as appropriate, with the shared services applications contained within the OMM CDF
- Must leverage, to the maximum extent practical, elements of the OMM SDK

- Must structure any newly developed capabilities as an augmentation of the existing set of class libraries when it is determined by Government review of the vendor design that reuse of specific elements of the code developed within this project is warranted
- Source code developed within Task 1 must compile within the Xamarin Integrated Development Environment (IDE) to a cross-platform (android & iOS) application that is capable of running on android/iOS devices on the DISA Approved Devices list at time of delivery of the prototype

Approaching the conclusion of Task 1, the JOMIS PMO plans to conduct an interim administrative review to assess performance to date and provide a go/no-go decision for the execution of Task 2.

Task 2:
Conduct the development work required to extend Theater Blood store-and-forward capabilities to a Windows operating system platform, including proposing additions and/or modifications to the CDE and CDF or the creation of new CDE/CDF capabilities to support Windows platform development, for the same capability area developed under Task 1. The functional prototype developed under Task 2 must meet the following requirements (subject to change):

- Must demonstrate the ability to meet Theater Blood capabilities documented in GFI 14 *TBLD IS Capabilities Table*, consistent with the legacy prototype Theater Blood mobile application provided to Offerors as GFI
- Must be fully compliant with DoD Modular Open Systems Architecture requirements
- Must be developed within the OMM CDE
- Must be developed using Agile Scrum methodology
- Must structure any newly developed capabilities into class libraries when it is determined by Government review of the vendor design that reuse of specific elements of the code developed within this project is warranted

Potential Follow-on Task:
There is potential for award of one or more follow-on tasks based on the success of Tasks 1 and 2 to complete the following (subject to change depending upon Government review of work completed on Tasks 1 and 2):
- Conduct the development work required to develop prototype Windows and mobile applications for the two capability areas not developed under Task 1 and Task 2.
- Conduct the development work required to transition the prototype applications into fully developed production-ready applications to be integrated into the operational medicine suite of IT systems and fielded to operational medicine users.

4.3 Preparation of the Proposal

The Technical Proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-19-09-TheaterBlood). 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).

- **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 submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) required. Separately, Section II: Cost Proposal **by Task** Formats either in Excel (.xlsx or .xls) or PDF format 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 6, "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 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.

4.7 Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

5 Government Furnished Information (GFI)

The Government is providing the following information to support proposal preparation. These items can be found in **Active Solicitations Folder in the Documents Library located on the MTEC members-only website**.

File Name	Description
1. TBLD M Source Code	Source code for previously developed Theater Blood mobile application prototype
2. pt1-NavigatingApplication 3. pt2-ReceiveProduct 4. pt3-ShipProduct 5. pt4-OtherInventory 6. pt5-Donation 7. pt6-Transfusion	Video demonstration of previously developed Theater Blood mobile application prototype

8. Operational Blood Management CONOPS	Operational Blood Management Concept of Operations (CONOPS)
9. Business Use Case TBLD	Business Use Case Document for Operational Blood Management
10. MCADS Development Management Plan v1.3.1 2018-08-03 11. MCADS Mobile Cookbook v1.1 2018-04-30 12. OpMed Mobile SDK Orientation v1.1 2019-03-15 13. OpMed Mobile SDK Service Layer Usage Guide v1.1 2019-04-19	OpMed Mobile SDK Documentation
14. TBLD IS Capabilities Table	Theater Blood capability/sub-capability descriptions
15. TBLDM Technical Requirements	JOMIS Non-functional Technical/Architecture Requirements

All of these items are provided as information to guide the development of proposals and subsequent work. Specific criteria against which the functionality will be evaluated will be developed during the User Story development process. JOMIS Non-Functional Technical Architecture requirements are provided to inform design considerations. The prototype will not be expected to meet all or any specific JOMIS Non-Functional Technical Architecture at the end of Task 2, but should be designed in a manner that does not preclude meeting those requirements in a production capability.

The Government will make available the following materials and information to Awardee(s):
- Access to the OMM CDE and associated project spaces, tools, etc.
- Sample blood product barcodes and Quick Response (QR) codes, sample Common Access Card (CAC) barcodes
- Relevant product documentation that may include DoD Architecture Framework (DODAF) artifacts and Interface Control Documents

6 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional

defense contractor participation, nonprofit research institution participation, all small business 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: • 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
FAIL	Offeror proposing an MTEC research project does **NOT** meet any of the following: • 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)*

6.1 Proposal Evaluation Process
Qualified applications will be evaluated by a panel of subject matter experts (SMEs) 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 2.4.

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.

6.2 Evaluation Factors
1. Understanding of and Compliance with Government Requirements
2. Adherence to DoD OSA Principles
3. Experience and Capabilities
4. Cost/Price

Table 2 explains the adjectival merit ratings that will be used for the non-cost/price factors.

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.

6.3 Evaluation Factor 1. Understanding of and Compliance with Government Requirements

Evaluation Factor 1 will be evaluated using the merit rating as shown in Table 2.

The proposal shall address each task area and provide sufficient detail to demonstrate a clear understanding of the Government's need, and provide a proposed approach to fulfill the need. The Offeror shall provide evidence of sufficient planning to show that proposed work will be accomplished as required and on schedule, utilizing all available resources.

The Offeror's proposal will be evaluated based on the degree to which the proposal demonstrates:

- Clear comprehension of functional capabilities required to fulfill Task 1 and Task 2
- Clear comprehension of the Theater Blood operating environment
- Clear comprehension of and compliance with, adherence to, and/or compatibility with applicable JOMIS Technical Architecture requirements
- A sound, clear technical approach that is likely to successfully satisfy required capabilities

6.4 Evaluation Factor 2. Adherence to DoD Modular Open Systems Approach (MOSA) Principles

Evaluation Factor 2 will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be evaluated based on the degree to which the proposal demonstrates:

- Clear comprehension of, and compliance with MOSA technical requirements
- An approach to identify and implement the appropriate use and augmentation of JOMIS OMM CDF elements to build proposed prototype applications
- An approach to identify the potential for and facilitate re-use of components of the solution that the Offeror proposes to build

6.5 Evaluation Factor 3. Experience and Capabilities

Evaluation Factor 3 will be evaluated using the merit rating as shown in Table 2.

The selected Offeror(s) must have relevant cross-platform development experience, mature Agile software development capabilities, and an understanding of the challenges of operating in a Department of Defense environment. The selected Offeror must be able to work as a part of a team, in full and open collaboration, with other participants from across Government, industry, and academia who may all play a role in the development, enhancement and continuing evolution of JOMIS capabilities.

The Offeror's proposal will be evaluated based on the degree to which the proposal demonstrates:

- Ability to execute the SOW based on the proposed project team's expertise, key personnel, and corporate experience.

- Experience implementing projects similar to that of the nature and scope described in this request for project proposal

- Experience working on collaborative development projects

- An approach that allows for collaboration with other stakeholders throughout the design, build, deliver and assess processes as described in this request for project proposal

- Experience implementing Agile development processes with business partner organizations

6.6 Evaluation Factor 4. 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 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.

6.7 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.

6.8 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.

7 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 and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to the MTEC Interim Executive Director and Program Manager, Ms. Kathy Zolman, 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.

8 Acronyms/Abbreviations

API   Application Programming Interface
ATI   Advanced Technology International
CAC   Common Access Card

CAS	Contract Accounting System
CDE	Collaborative Development Environment
CDF	Collaborative Development Framework
CDR	Critical Design Review
CM	Consortium Manager
CMA	Consortium Member Agreement
CONOPS	Concept of Operations
CONUS	continental United States
DHA	Defense Health Agency
DHMS	Defense Healthcare Management Systems
DHP	Defense Health Program
DIL	Disconnected, Intermittent, Limited bandwidth
DISA	Defense Information Systems Agency
DoD	Department of Defense
DODAF	DoD Architecture Framework
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
GFI	Government Furnished Information
GU	Genitourinary
HCD	Health Care Delivery
HIPAA	Health Insurance Portability and Accountability Act
IDE	Integrated Development Environment
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IR&D	Independent Research and Development
JOMIS	Joint Operational Medicine Information Systems
M	Millions
MedC2	Medical Command and Control
MEDLOG	Medical Logistics
MedSA	Medical Situational Awareness
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
OMM	Operational Medicine Mobile
OpMed	Operational Medicine
ORP	Office of Research Protections, USAMRMC
PDR	Preliminary Design Review
PEO	Program Executive Office
PM	Patient Movement

PMO	Program Management Office
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
PoP	Period of Performance
PPG	Proposal Preparation Guide
QR	Quick responses
R&D	Research and Development
RDT&E	Research, Development, Test and Engineering
RPP	Request for Project Proposals
SDD	Software Design Description
SDK	Software Developers Kit
SDP	Software Development Plan
SIP	Software Installation Plan
SME	Subject Matter Expert
SOW	Statement of Work
SRS	Software Requirements Specification
SSP	Software Sustainability Package
STD	Software Test Description
STP	Software Test Plan
STR	Software Test Report
SUM	Software User Manual
SVD	Software Version Description
TBLD	Theater Blood
TMDS	Theater Medical Data Store
TMIP-J	Theater Medical Information Program – Joint
TRL	Technology Readiness Level
TTD	Transfusion Transmittable Disease
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government

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 hardware/software to be provided to the Government as a result of this project shall be identified. 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

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	1st 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	$ -		$ -

		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 **(Prior to the POP End**)	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.)

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*)

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)