Request for Project Proposals

Solicitation Number: MTEC-23-10-PTSD-RegulatorySponsor

"Department of Defense Posttraumatic Stress Disorder Adaptive Platform Trial Regulatory Sponsor Partner"

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

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Enhanced White Paper Due Date: July 7, 2023
Noon Eastern Time

Table of Contents

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 Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) 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) engage in 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.

MTEC is a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, "nontraditional" defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at https://mtec-sc.org/.

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 4022 (formerly 10 USC 2371b), the MTEC OTA enables the Government to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. As defined in the DoD OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

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 in support of the US Army Medical Materiel Development Activity (USAMMDA). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 4022. Strategic oversight for the award(s) supported by this RPP will be provided by USAMMDA.

The overall objective of effort is to identify organizations who are willing and able to fulfill responsibilities as the regulatory sponsor of clinical trial protocol S-21-02 entitled, "*A Phase 2, Multi-Center, Multi-Arm, Randomized, Placebo-Controlled, Double-Blind, Adaptive Platform Study to Evaluate the Safety, Tolerability, and Efficacy of Potential Therapeutic Interventions in Active-Duty Service Members and Veterans with Posttraumatic Stress Disorder*" (NCT05422612). Expected enrollment for this trial is expected to begin in June 2023. The Department of Defense (DOD) is funding and has established this posttraumatic stress disorder (PTSD) adaptive platform trial (APT). The team is now seeking interested partners to serve as the regulatory sponsor and holder of the existing Master Protocol Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA).

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing an accelerated approach to award for this RPP. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP. Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in **Section 8 of the RPP**. Enhanced White Papers that fail to follow the mandatory format may be eliminated from the competition during the CM's preliminary screening stage (see **Section 5 of the RPP** for more details on the Selection process). The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

*Note that the terms "Enhanced White Paper" and "Proposal" are used interchangeably throughout this RPP.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has funds available for this effort. Offerors are expected to propose budgets they believe are reasonable for the scope of the Regulatory Sponsor role based on the expectations described within this RPP.

MTEC expects to make **a single award** to a qualified Offeror to accomplish the scope of work with a Period of Performance not to exceed **26 months**. The POP for the MTEC partners started in 2020 with a current end date of November 2025, but may be extended pending continued future requirement and available funding.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see **Section 8 of this RPP**). The Government will evaluate Enhanced White Papers and will select those that represent the best value using the evaluation criteria in **Section 5 of this RPP**. Offerors whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2 (and may be required to submit additional documentation or supplemental information such as those examples listed under Section 4.2). Notification letters will contain specific Stage 2 proposal submission requirements.

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 4022 section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award (RPA) issued under the member's Base Agreement. 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 Enhanced White Paper 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 Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

As noted above, this project will be funded through a Research Project Award with Terms and Conditions terms and conditions specific to the project. Any specific terms negotiated at the RPA level will take precedence over the terms and conditions in the MTEC Base Agreement.

2.4. Proposers Conference

MTEC intends to host a Proposers Conference that will be conducted via virtual webinar on **Thursday, June 15, 2023 at 11:00am – 12:00pm Eastern Time**. Further instructions on registering for the Proposers Conference will be forthcoming via email. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the Technical Requirements outlined in **Section 3 of this RPP**. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions responses.

2.5. Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal 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. **Please mark all Confidential or Proprietary information as such.** 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. Therefore, 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 entities. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements and Organizational Conflict of Interest 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, which may include contractor support personnel serving as nongovernmental advisors, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

2.6. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit a White Paper. Offerors submitting White Papers as the prime performer must be MTEC members of good standing at least 3 days prior to submission of the White Paper. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

2.7. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP.* 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 an in-kind contribution (see **Section 7.4 of the PPG** for definitions); 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.).

2.8. Cost Sharing Requirements

In order to be compliant with the statute for awarding prototype projects, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG (summarized in Table 1 of this RPP)**. For more information regarding cost share, please see **Section 7.4 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award. Unless required to meet one of the conditions specified in Table 1 of this RPP, cost share is not necessary.

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 2% of the total funded value of each research project awarded. Such deposits shall be due no later than 90-days after the Research Project Award is executed. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not “Members in good standing”.

2.10. Intellectual Property and Data Rights

IP and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement. Specifically-negotiated terms that are finalized in any resultant Research Project Award take precedence over terms of the Base Agreement. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and Data Rights as modified by the specifically-negotiated IP and Data rights terms in the Research Project Award as follows: **It is anticipated that the government will exclusively own all Intellectual Property and will have exclusive rights in all Research Project Awardee data developed in the course of performing the work defined under the Research Project, including the infrastructure, biological samples and data, and clinical trial data**.

- **"Data"** means computer software, computer software documentation, form, fit and function data **(including key system utilities and macros)**, and technical data, including infrastructure.

- **"Technical data"** means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information. "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.

- **"Infrastructure"** includes, but is not limited to, the governance structure and associated charters; information produced by or with input from governance structure bodies; information and materials produced by or with Research Project Awardee subcontractors including agreements and budgets; study documents developed with or without input from governance structure bodies (e.g. protocols, statistical analysis plans, data flow plans, site feasibility documents, site and rater training plans and materials, investigator meeting presentations); site lists, intelligence relationships, contracts and database; program standard operating procedures (SOPs) including those developed with quality assurance (QA) vendor; all study materials, presentations, brochures, logos, and trademark; all statistical Research Project Awardee outputs including, simulations and analysis plans for this study.

The Awardee will not own the IP developed during the period of performance. The rights to the data will be restricted to use during the active agreement period of performance solely for this effort. The Government may negotiate different IP ownership or data rights, including exclusive licensing thereof, as called for in MTEC Base Agreement sections 9.3.4 and 10.7, with to-be-determined partners for the development of and regulatory approval of biological markers or drugs resulting from the research herein.

It is anticipated that USAMMDA will control the distribution of data to other organizations, and use of the data, including after study closeout, requires agreement by USAMMDA. Written publications, oral publications, and/or press releases that may result from work performed under the Research Project requires agreement by USAMMDA prior to submission for publication or release.

See **Attachment 6 of the PPG** for more detail. Note that as part of the Stage 1 of the RPP process (submission of an Enhanced White Paper), Offerors shall complete and submit **Attachment 6 of the PPG** (Intellectual Property and Data Rights) as an appendix to the Enhanced White Paper with the Signature of the responsible party for the proposing Prime Offeror.

2.11. Expected Award Date

Offerors should plan on the period of performance beginning September of 2023 (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.

2.12. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward its selections to the MTEC CM to notify Offerors. All Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next stage of the process.

Offerors are hereby notified that once an Enhanced White Paper has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1. Background

CLINICAL PROBLEM:

PTSD is a chronic and disabling psychiatric disorder with a lifetime prevalence of approximately 7% in the United States. PTSD is characterized by intrusive thoughts, nightmares and flashbacks of past traumatic events, avoidance of reminders of trauma, hypervigilance, and sleep disturbance, all of which lead to considerable social, occupational, and interpersonal dysfunction. While patients suffering from PTSD all exhibit some element of the cardinal features as defined by the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, there is significant heterogeneity in clinical presentation. Certain symptoms may be more prominent in some patients than others, and most patients have at least one additional psychiatric comorbidity such as insomnia, depressive disorders, anxiety disorders, or substance use disorders. Efforts have been made to categorize patients based on clusters of symptoms and comorbidities, but the utility of such subtypes for diagnosis, prognosis, or for treatment guidance is not yet validated.

PTSD symptoms can persist for years or decades after the traumatic event; only one-third of patients recovered at the one-year follow-up and one-third remained symptomatic 10 years later. PTSD is associated with poor social support, higher healthcare utilization, and may be associated with increased mortality.

Therefore, the goal of the DOD's PTSD-Drug Treatment (DT) program, led by the U.S. Army Medical Materiel Development Activity's (USAMMDA) Warfighter Brain Health Project Management Office (WBH PMO), is to increase the medical readiness of U.S. Warfighters by developing drug therapies for the treatment of PTSD.

BACKGROUND ON THE DOD PTSD APT:

Since 1987 there have been over 130 clinical trials conducted in PTSD with more than 48 drugs or drug combinations, encompassing more than 30 mechanisms of action, with little to no return on investment. Most of these trials studied one drug at a time, without the use of biological information to define the sample of patients with PTSD most likely to respond to the drug's mechanism of action either prospectively or retrospectively. Given that PTSD is biologically complex with multiple integrated, dysregulated biological systems leading to clinical presentation, a different approach to the development of drug treatments is necessary. Innovative clinical trial designs, such as master protocols and adaptive protocol elements, are efficient, cost-effective, and have increasingly been used in other indications to address complex disorders, with U.S. FDA support.

An APT is a type of master protocol with adaptive protocol elements. The master protocol describes default procedures and analyses for all therapies within the trial. Specific cohorts of the trial are described in appendices and provide details specific to each cohort. These might include, but are not limited to, deviations in the default trial population or additional safety analyses specific to a cohort that might need to be conducted.

The DOD PTSD APT is a unique trial that utilizes an adaptive platform design to answer multiple scientific questions simultaneously and more efficiently. The framework allows for the evaluation of multiple potential treatments for PTSD, and interrogation of the biological and environmental factors that underpin drug effectiveness in PTSD biomarker subtypes. The first three drugs to be tested in the DOD PTSD APT are fluoxetine, vilazodone, and daridorexant. All three drugs are currently FDA-approved for non-PTSD indications. In the future, additional drugs that will be tested (pending funding availability) may include generic drugs, drugs under marketing exclusivity, or new molecular entities.

In addition to the efficiencies gained by simultaneous testing of multiple treatments, this study aims to address the clinical and biological heterogeneity of PTSD in military populations and develop a precision medicine approach through the identification, characterization, and validation of candidate biomarkers to identify the most effective therapy for each patient's unique biological or clinical characteristics. These biomarkers, whether evaluated together or individually, within or across biomarker modalities, may be diagnostic of PTSD subtypes, predictive of treatment response, surrogate/monitoring markers of clinical efficacy, or pharmacodynamic markers of intervention effects.

DOD PTSD APT GOVERNANCE STRUCTURE AND CURRENT PARTNERS

LEAD ORGANIZATION: USAMMDA is the funding and management organization of the DOD PTSD APT. The USAMMDA WBH PMO PTSD-DT program Product Manager (PdM) is responsible for the cost, schedule, and performance of the DOD PTSD APT and all technical decisions. The WBH PMO PTSD-DT program partnered through a variety of agreements with a team of experts in operational excellence, platform trial statistical methodology, drug development, and PTSD clinical assessment and pathophysiology to design and execute the DOD PTSD APT study. The

team of experts that support the study through various committees and working groups are outlined below. ***NOTE: The Government does not indemnify its partners.***

CURRENT REGULATORY SPONSOR: The current regulatory sponsor is The Surgeon General, Department of the Army (DA). The U.S. Army Medical Research and Development Command (USAMRDC) Office of Regulated Activities (ORA) provides regulatory-sponsor support and oversight for the trial. USAMMDA has partnered with USMRDC ORA for their support through an interagency agreement. It is the intent that the new regulatory sponsor, sought through this RPP, will replace The Surgeon General, DA as the regulatory sponsor of the DOD PTSD APT.

EXECUTIVE COMMITTEE: The study's central governance body is the APT for PTSD Executive Committee (APEC). The APEC is chaired by the DOD PTSD WBH PMO and includes leads from each of the study partners and working groups. The APEC provides expert insight and advice on major study design elements to the PdM. The APEC optimizes the study design and executes operational tasks to meet the study objectives.

MTEC: Through MTEC and the OTA, USAMMDA has partnered with Berry Consultants, Citeline, and Pharmaceutical Product Development (PPD) to perform the following functions in support of the DOD PTSD APT.

- STATISTICAL MODELING: Berry Consultants, LLC is responsible for operationalizing and executing the statistical simulations and calculations, and developing key documents (e.g., statistical sections of the master protocol, statistical analysis plan, operational plan) to inform the DOD PTSD APT design, initiation, and execution.

- DRUG SELECTION: Citeline is responsible for operationalizing and executing the drug selection process in consultation with the Drug Selection Working Group, and for providing input to the APEC for initial and continual assessments of interventions to be tested in the DOD PTSD APT.

- CLINICAL RESEARCH ORGANIZATION (CRO): PPD, LP is responsible for operationalizing the DOD PTSD APT design by establishing the clinical trial infrastructure and executing the DOD PTSD APT in alignment with guidance from the APEC.

SPONSOR'S OFFICE TECHNICAL REPRESENTATIVE (SOTR): The WBH PMO PdM serves as the SOTR for all MTEC partners working on the DOD PTSD APT, including Berry Consultants, Citeline, and PPD. The SOTR's responsibilities include verifying that MTEC partners perform the technical requirements outlined in their scope of work in accordance with the terms, conditions, and specifications of their awards; acceptance for the Government of services performed, i.e., approval of deliverables; invoice review and approval; and monitoring compliance with MRDC Office of Human Research Oversight requirements. The SOTR will serve the same function for future MTEC awards working on the DOD PTSD APT, such as the regulatory sponsor (subject of this RPP).

ADVISORY TEAM AND WORKING GROUPS: One steering committee and three Working Groups (WGs) include DOD expertise to ensure the testing design and execution align with active-duty military requirements. The WGs operate at both the strategic and tactical levels and provide subject matter expertise in PTSD clinical trials. All WGs review and provide input into the master protocol, drug appendices, and related key study documents.

- The Joint Steering Committee operates at a strategic level to provide consultation to the PdM to ensure a successful program and to facilitate coordination across government entities, as well as connections to individuals or organizations who may be helpful. The members are from the DOD, the US Department of Veterans Affairs, the FDA, and several National Institutes of Health components.

- The Drug Selection WG is comprised of subject matter experts in clinical pharmacology and psychopharmacology, who review and provide feedback on the deliverables from the MTEC Drug Selection Vendor (via DOD coordination). This WG provides input to the APEC for their recommendations to the PdM for drugs and doses to be tested in the DOD PTSD APT. During study execution, the DSWG will work with the APEC to inform their drug selection recommendations beyond the initial set of drugs to be tested. USAMMDA has partnered with the San Francisco Veterans Administration through an interagency agreement for contracting with the Drug Selection WG members.

- The Clinical WG members have significant expertise in developing, validating, and implementing clinical assessments, including cognitive, functional, and Quality of Life assessments, primarily in military samples. This WG provides input to the APEC for their recommendations on key protocol elements and development of key study documents during the design and execution of the trial that align with the study objectives, including inclusion/exclusion criteria, inclusion of clinical assessments, and identification of clinical endpoints. The CRO, PPD, has subcontracted with individual consultants for the Clinical WG.

- The Biomarker WG has expertise in a variety of specific biomarker modalities. This group provides input to the APEC for their recommendation of key protocol elements that align with the study objectives, including an integrated approach to optimal collection and analysis of PTSD-relevant multi-modal biomarker data. This WG will also review emerging biomarker data from main stage analyses to inform precision medicine objectives, potential diagnostic development, and work with the APEC to inform their drug selection recommendations beyond the initial set of drugs to be tested. The CRO, PPD, has subcontracted with individual consultants for the Clinical WG.

3.2. Scope of Work

This RPP focuses on identifying an organization capable of serving as the regulatory Sponsor to hold the existing Master Protocol IND application to the U.S. FDA for the DOD PTSD APT,

scheduled to begin enrollment the second quarter of 2023. The DOD WBH PMO requires a partnership with a regulatory Sponsor who will include the WBH PMO as part of the Sponsor Organization.[1,2]

The replacement regulatory sponsor will work closely with the WBH PMO PTSD-DT PdM, and must be willing and able to interact with the other partners described above, with the exception of the current regulatory sponsor, in coordination with the WBH PMO. It is the intent that a contractual relationship with the new regulatory sponsor would be executed under the MTEC OTA. Interested parties are encouraged to review the MTEC Base Agreement, which includes the overarching terms and conditions from the OTA for prototype projects between the Government and MTEC that all Research Project Awardees are expected to agree to. The MTEC Base Agreement can be found on the MTEC Website (within the Documents Library: https://www.mtec-sc.org/documents-library/) and the Members-Only website at www.mtec-sc.org .

3.3. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP. Potential follow-on work may include tasks related to advancement of prototype maturity, including the potential for the Awardee to take on more regulatory responsibilities to support the conduct of the study in addition to the sponsorship role described in this RPP.

3.4. Restrictions on Human Subjects

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) prior to research implementation. The requested scope of work under this RPP does not include conducting research involving humans, however OHRO determination that research involving human subjects is not being conducted may be required.

The Awardee shall ensure any required USAMRDC OHRO determination is attained. Offerors shall include OHRO review and determination in the SOW/Milestones Table submitted with the Proposal, as applicable.

[1] 21 CFR 312.3 indicates a "Sponsor" may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.
[2] FDA's Guidance for Clinical Trial Sponsors (March 2006) is relevant to parties who participate in leadership roles in a clinical investigation other than sponsors, including funding organizations and/or others who share decision-making authority for a trial. The guidance indicates Sponsor (see 21 CFR 312.2 definition of Sponsor) interaction with the DSMB to provide important information regarding goals, plans, schedule, and resources, and to address DSMB questions when reviewing interim comparative data, has significant advantages.

4 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced White Papers should be submitted by the date and time specified on the cover page using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission. The Offeror shall include MTEC Solicitation Number (**MTEC-23-10-PTSD-Regulatory Sponsor**) in the Enhanced White Paper.

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory**. Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit Enhanced White Papers 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 DoD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Enhanced White Paper

Offerors submitting an Enhanced White Paper, inclusive of a Rough Order of Magnitude cost/price estimate, in response to this RPP shall prepare all documents in accordance with the following instructions:

Offerors should submit Word (*.doc or *.docx) files. ZIP files and other application formats (*.pptx, *.ppt, *.xlsx, *.xls, or *.pdf) are not acceptable. All files must be print-capable, searchable, and without a password required. Filenames must contain the appropriate filename extension (*.docx, *.doc). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. 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. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

Required Submission Documents (5): Submitted via BIDS (5MB or lower per document)

- **Enhanced White Paper:** one Word (*.doc or *.docx) document **(Section 8 of this RPP)**
- **Warranties and Representations:** one Word (*.doc or *.docx) document **(Attachment 3 of the PPG)**

- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word (*.doc or *.docx) document **(Addendum 1 of this RPP)**
- **Intellectual Property and Data Rights Assertions:** one Word (*.doc or *.docx) document **(Attachment 6 of the PPG)**
- **Resumes of Key Personnel:** one Word (*.doc or *.docx) document

The Enhanced White Paper Format

1. Limited to six (6) pages, *excluding the cover page, Warranties and Representations, references, SOW/MPS, resumes of key personnel, and Intellectual Property and Data Rights Assertions.*
2. 12-point Arial font, smaller font may be used in figures and tables, but must be clearly legible
3. Single-spaced, single-sided, 8.5 inches x 11 inches.
4. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch

Enhanced White Papers and Appendices exceeding the page limitations and/or the file size specified above may not be accepted. Each document shall be uploaded to BIDS separately (see Attachment 7 of the PPG for BIDS instructions).

FOR INFORMATION ONLY: Please note a full Cost Proposal will be requested if the Enhanced White Paper is recommended for funding (see Section 4.3 for additional details). Furthermore, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission may be requested after completion of the technical evaluation.

The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided (as part of the Selection Notification described in 2.12).

4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Paper revisions and/or supplemental information, such as those examples listed in the section above, based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (2): Submit to mtec-contracts@ati.org

- **Section I: Cost Proposal Narrative:** one Word (*.doc or *.docx) document
- **Section II: Cost Proposal Formats:** one Word (*.doc or *.docx) or Excel (*.xlsx or *.xls) document

See below for additional instructions. Also refer to **Addendum 2 of this RPP** for details on how the full Cost Proposals will be evaluated.

The Cost Proposal shall be submitted in two separate sections. One Word (.docx or .doc) file for **Section I: Cost Proposal Narrative** and one Word (*.doc or *.docx) or one Excel (.xlsx or .xls) file for **Section II: Cost Proposal Formats** is required. Please refer to Section 7 of the PPG for more information.

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 Proposal formats provided by MTEC are **NOT** mandatory.

Each cost proposal 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. Refer to the MTEC PPG for additional details.

Those Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects of the Stage 2 requirements are clearly understood by both parties.

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

The cost of preparing Enhanced White Papers and Cost Proposals in response to this RPP is not allowable as a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.9 of this RPP) is not allowable as a direct charge to any resulting award or any other contract.

4.5. 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.

4.6. Telecommunications and Video Surveillance

As stated in Section 6.1.2 of the MTEC PPG, per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, “Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment” is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation, as required by the provision, to the CM.

5 Selection

5.1 Preliminary Screening

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers that do not meet the requirements of the RPP may be eliminated from the

competition or additional information may be requested by the CM. Additionally, 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 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 Section 3 of the PPG). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Section 3 of the PPG) will be determined based upon the ratings 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 Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • 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 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 • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2 Enhanced White Paper (Stage 1) Evaluation

The CM will release all Enhanced White Papers that pass the preliminary screening (described above and in Table 1) to the Government for full evaluation. Evaluation of Enhanced White Papers will be based on an independent, comprehensive review and assessment of the work

proposed against the stated source selection criteria and evaluation factors. This process may involve the use of contractors as subject matter expert (SME) consultants or reviewers.

The Government will evaluate each Enhanced White Paper against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

The evaluation factors and evaluation criteria are described below (of equal importance).

Evaluation Factors

1. **Experience**
2. **Approach and Feasibility**
3. **Programmatic Alignment**

Evaluation Factor 1 - Experience

The Offeror's submission will be assessed for:

a) Demonstration of experience as the regulatory sponsor and IND holder for Master Protocols.
b) Demonstration of appropriate qualifications and expertise of the personnel and organization(s) that will perform the proposed work.

Evaluation Factor 2 - Approach and Feasibility

The Offeror's submission will be assessed for:

a) Demonstration of an understanding of the objective, including a clear description of the governance approach that:
    - aligns with the Sponsor's Organization concept
    - aligns with 21 CFR 312.3 and the FDA's Guidance for Clinical Trial Sponsors (March 2006)
    - describes the approach to fulfilling additional regulatory oversight responsibilities for trial operations including regulatory submissions, clinical aspects, site qualification and management, investigational product manufacturing and supply, and data management.
    - details minimum requirements for oversight, including contractual relationships, if applicable
b) Likelihood of successfully achieving the objective as defined in this RPP within an acceptable timeframe.

Evaluation Factor 3 - Programmatic Alignment

The Offeror's submission will be assessed for:

a) Ability to fulfill the Sponsor's responsibilities without Government indemnification.

b) Acceptability of requirements for sponsorship related to liability or indemnification (e.g., for testing of drug product that is provided by an industry partner).
c) How well the Offeror's approach aligns with the IP and Data Rights terms outlined in Section 2.10 of the RPP and the degree to which the Offeror's approach impacts the Government use of IP and data.
d) Reasonableness of the ROM.

Table 2 explains the adjectival merit ratings that will be used for the Evaluation 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.

Please also refer to Section 5.3 for definitions of general terms used in technical evaluations.

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. 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)***

In rare cases, the following recommendation may be provided: "Recommendation Undetermined." This is reserved for situations in which additional information/documentation is

needed by the Government evaluators before finalizing a recommendation to one of those listed above and is intended to facilitate the release of all evaluator comments within the BIDS System.

The RPP review and award process may involve the use of contractor SMEs serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information contained in the Enhanced White Paper as outlined in Section 2.5.

5.3 Definition of General Terms Used in Evaluations

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.

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 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, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Chief Science Officer, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@mtec-sc.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

APEC	APT for PTSD Executive Committee
APT	Adaptive Platform Trial
ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, Manufacturing, and Controls
CRO	Clinical Research Organization
DA	Department of the Army
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DoD	Department of Defense
DODI	Department of Defense Instruction
DT	Drug Treatment
EC	Ethics Committee
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Act
ODC	Other Direct Costs
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORA	Office of Regulated Activities
OTA	Other Transaction Agreement
PDF	Portable Document Format
PdM	Product Manager
POC	Point-of-Contact
PoP	Period of Performance
PPD	Pharmaceutical Product Development
PPG	Proposal Preparation Guide

PTSD	Posttraumatic stress disorder
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOTR	Sponsor's Office Technical Representative
SOW	Statement of Work
TORO	Transfer of Regulatory Obligations
TRL	Technology Readiness Level
USAMMDA	United States Army Medical Materiel Development Activity
USAMRDC	United States Army Medical Research and Development Command
WBH PMO	Warfighter Brain Health Program Management Office
USG	U.S. Government
WG	Working Group

8 Enhanced White Paper Template

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

Unique Entity ID: [UEI]
CAGE code: [CAGE code]

[Title of Enhanced White Paper]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that, if selected for award, the Offeror will become a member in good standing of the MTEC consortium prior to the Full Cost Proposal Submission.

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:
This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Enhanced White Paper]

Content must include answers to the following prompts. Please number answers to align with prompts one through 12.

1. Are you a current member of MTEC? If not, would you be willing to become a member of MTEC if selected to serve as the regulatory sponsor of the DOD PTSD APT?
2. Do you have experience as the regulatory sponsor and IND holder for Master Protocols? If so, please describe your experience.
3. Are you currently available to fulfill the Sponsor's responsibilities? If not, when will you be available?
4. Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
5. Do you require a direct contractual relationship with the CRO or other vendors?
6. If a direct contractual relationship (see above question) is not required, describe minimum requirements for oversight, e.g., Transfer of Regulatory Obligations (TORO).
7. Describe a proposed governance approach that fulfills regulatory oversight responsibilities and aligns with 21 CFR 312.3 and the FDA's Guidance for Clinical Trail Sponsors (March 2006), as referenced in the objective of this RPP.
    a. Describe how WBH PMO, including the PdM/SOTR, will be included in key trial decisions, and Data Safety Monitoring Board discussions and decision-making processes.
    b. Describe the approach to fulfilling additional regulatory oversight responsibilities for trial operations including regulatory submissions, clinical aspects, site qualification and management, investigational product manufacturing and supply, and data management.
8. Are you able to fulfill the Sponsor's responsibilities without Government indemnification?
9. Describe any requirements for taking on sponsor responsibilities related to liability or indemnification (e.g., for testing of drug product that is provided by an industry partner).
10. Are you able to agree to all of the intellectual and data rights terms specified in Section 2.10 of this RPP? If not, please describe.
11. Provide a cost estimate that includes yearly rough order magnitude pricing using the following template:

	Year 1 Estimate	***Year 2 Estimate***	***Year 3 Estimate***	***Total Estimate***
Labor	*$ 25,000*	*$ 25,000*	*$ 25,000*	*$ 75,000*
Labor Hours	*250.0 hrs*	*250.0 hrs*	*250.0 hrs*	*750.0 hrs*
Subcontractors	*$ 12,500.00*	*$ 12,500.00*	*$ 12,500*	*37,500.00*
Subcontractors Hours	*125.0 hrs*	*125.0*	*.0 hrs*	*375.0 hrs*
Consultants	*$ 2,500.00*		*$ 2,500.00*	*$ 7,500.00*
Consultants Hours	*25*	*25.0 hrs*	*25.0 hrs*	*75.0 hrs*
Material/Equipment	*$ 18,*	*$ 18,750.00*	*$ 18,750.00*	*$ 56,250.00*
Other Direct Costs	*$ 250.00*	*$ 250.00*	*$ 250.00*	*$ 750.00*

EXAMPLE

Travel	*$ 1,250.00*	*$ 1,250.00*	*$ 1,250.00*	*$ 3,750.00*
Indirect costs	*$ 12,050.00*	*$ 12,050.00*	*$ 12,050.00*	*$ 36,150.00*
Total Cost	*$ 72,300.00*	*$ 72,300.00*	*$ 72,300.00*	*$ 216,900.00*
Fee	*$ 0.00*	*$ 0.00*	*$ 0.00*	*$ 0.00*
Total Cost (plus Fee)	*$ 72,300.00*	*$ 72,300.00*	*$ 72,300.00*	*$ 216,900.00*

12. The Offeror must provide a **brief** rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Warranties and Representations: (template provided in Attachment 3 of the PPG)

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

Appendix 2: Statement of Work (template provided in Addendum 1 of this RPP)

- Provide a draft Statement of Work as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Enhanced White Paper for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below.
- The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule (MPS). Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

Appendix 3: Intellectual Property and Data Rights Assertions (template provided in Attachment 6 of the PPG)

- Provide a completed Intellectual Property (IP) and Data Rights Assertion document as one Word or PDF document (See Attachment 6 of the PPG for more information and template).

Appendix 4: Resumes of Key Personnel

- Include the resumes of key lead MTEC member organization, team members, subcontractor and university personnel who will be assigned to and work on this project if selected. Indicate what percentage of their total available work time each will devote to this project.
- The resume of each key person is limited to 3 pages. There is no limit on the number of resumes included. There is no required template.

Addendum 1 – Statement of Work (SOW)/Milestone Payment Schedule (MPS)

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

Proposal Number: (RPP Number)
Organization:
Title: (Proposed Project Title)
ACURO and/or HRPO approval needed: (If you're conducting any animal or human testing, you will need to submit for the appropriate Army Approvals)

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 MS Word (*.doc or *.docx) format. At a minimum, the following deliverables will be required:

- Deliverable 1: Non-Disclosure/Non-Use Agreement. The awardee shall sign and submit a Non-Disclosure Statement and shall also ensure that all staff including all subcontractors and consultants performing on any task/delivery order execute and adhere to the terms of the non-disclosure statement, protecting the procurement sensitive information of the DoD and proprietary information.

- Deliverable 2: Spend Plan. The awardee shall provide a Spend Plan which details how they expect to incur and invoice for costs against the contract. Include detailed costs to be incurred monthly by fiscal year (1 October – 30 September) through the PoP, starting at the award date. The Spend Plan total shall match the total costs proposed for the entire award in the Cost/Pricing Sheet. The Spend Plan shall be updated as necessary throughout the duration of the project/award. The awardee shall report actual progress against the Spend Plan in the Monthly Report.

- Deliverable 3: Communication Plan. A Communication Plan shall define who should be given specific information, when that information should be delivered and what communication channels will be used to deliver the information.

- Deliverable 4: Responsibility Assignment Matrix. A Responsibility Assignment Matrix in the form of a RACI matrix shall clarify individual or group roles for project tasks by assigning one of four roles: Responsible (R), Accountable (A), Consult (C), and Inform (I).

It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Site Locations (Provide a list of site locations identifying where all project work is to be conducted. Site locations should be inclusive of the Prime Organization, Sub Contractors, Contract Research Organizations, Military Labs and/or Units. Only add information for an additional site if that site is receiving funding to conduct research as outline in the SOW. Delete "Site 2" header if not used.)

Site 1:	Institution Name	Site 2*:	Institution Name
	Address for primary site		Address for Org #2
	PI: John Doe		Partnering/Site PI/POC: Jane Smith

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 $1M 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, Monthly Reports which include both Technical Reports and Expense Status Reports (due the 25th of each month), Annual Reports, Final Technical Report, and Final Business Status Report.

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	1/1/2020	$20,000		$20,000
2	N/A	Monthly Report 1 (January, Technical and Business Reports)	1/28/2020	$ -		$ -
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	N/A	Monthly Report 2 (February, Technical and Business Reports)	2/28/2020	$ -		$ -
6	N/A	Monthly Report 3 (March, Technical and Business Reports)	3/28/2020	$ -		$ -
7	3	Submission of Investigational New Drug application to the US FDA	4/28/2020	$210,757	$187,457	$398,214
8	N/A	Monthly Report 4 (April, Technical and Business Reports)	4/28/2020	$ -		$ -
9	N/A	Monthly Report 5 (May, Technical and Business Reports)	5/28/2020	$ -		$ -
10	N/A	Monthly Report 6 (June, Technical and Business Reports)	6/28/2020	$ -		$ -
11	N/A	Monthly Report 7 (July, Technical and Business Reports)	7/25/2020	$ -		$ -
12	N/A	Monthly Report 8 (August, Technical and Business Reports)	8/28/2020	$ -		$ -
13	N/A	Monthly Report 9 (September, Technical and Business Reports)	9/28/2020	$ -		$ -

14	4	Toxicity Studies	10/1/2020	$63,227		$63,227
15	N/A	Monthly Report 10 (October, Technical and Business Reports)	10/28/2020	$ -		$ -
16	5	FDA authorization trial	11/28/2020	$84,303		$84,303
17	6	Research staff trained	11/28/2020	$ -		$ -
18	7	Data Management system completed	11/28/2020	$ -		$ -
19	N/A	Monthly Report 11 (November, Technical and Business Reports)	11/28/2020	$ -		$ -
20	N/A	Monthly Report 12 (December, Technical and Business Reports)	12/28/2020	$ -		$ -
21	8	1st subject screened, randomized and enrolled in study	1/1/2021	$150,000	$187,457	$337,457
22	N/A	Annual Report 1	1/28/2021	$ -		$ -
23	N/A	Monthly Report 13 (February, Technical and Business Reports)	2/28/2021	$ -		$ -
24	9	Completion of dip molding apparatus	3/1/2021	$157,829	$187,457	$370,286
25	N/A	Monthly Report 14 (March, Technical and Business Reports)	3/28/2021	$ -		$ -
26	N/A	Monthly Report 15 (April, Technical and Business Reports)	4/28/2021	$ -		$ -
27	N/A	Monthly Report 16 (May, Technical and Business Reports)	5/28/2021	$ -		$ -
28	10	Assess potential toxicology	6/1/2021	$157,829		$157,829
29	N/A	Monthly Report 17 (June, Technical and Business Reports)	6/28/2021	$ -		$ -
30	N/A	Monthly Report 18 (July, Technical and Business Reports)	7/28/2021	$ -		$ -
31	N/A	Monthly Report 19 (August, Technical and Business Reports)	8/28/2021	$ -		$ -
32	N/A	Monthly Report 20 (September, Technical and Business Reports)	9/28/2021	$ -		$ -
33	11	Complete 50% patient enrollment	10/1/2021	$350,000	$187,457	$537,457
35	N/A	Monthly Report 21 (October, Technical and Business Reports)	10/28/2021	$ -		$ -
36	N/A	Monthly Report 22 (November, Technical and Business Reports)	11/28/2021	$ -		$ -

37	N/A	Monthly Report 23 (December, Technical and Business Reports)	12/28/2021	$ -		$ -
34	N/A	Annual Report 2	1/28/2022	$ -		$ -
38	N/A	Monthly Report 24 (February, Technical and Business Reports)	2/28/2022	$ -		$ -
40	12	Electronic Report Forms Developed	3/1/2022	$315,658	$187,457	$503,115
41	N/A	Monthly Report 25 (March, Technical and Business Reports)	3/28/2022	$ -		$ -
42	N/A	Monthly Report 26 (April, Technical and Business Reports)	4/28/2022	$ -		$ -
43	N/A	Monthly Report 27 (May, Technical and Business Reports)	5/28/2022	$ -		$ -
44	N/A	Monthly Report 28 (June, Technical and Business Reports)	6/28/2022	$ -		$ -
45	N/A	Monthly Report 29 (July, Technical and Business Reports)	7/25/2022	$ -		$ -
46	13	Complete 100% patient enrollment	8/1/2022	$315,658	$187,457	$503,115
47	N/A	Monthly Report 30 (August, Technical and Business Reports)	8/28/2022	$ -		$ -
48	N/A	Monthly Report 31 (September, Technical and Business Reports)	9/28/2022	$ -		$ -
49	N/A	Monthly Report 32 (October, Technical and Business Reports)	10/28/2022	$ -		$ -
50	14	Report results from data analysis	11/1/2022	$157,829		$157,829
51	N/A	Monthly Report 1 (November, Technical and Business Reports)	11/28/2022	$ -		$ -
51	N/A	Final Reports (Prior to the POP End) – Final reports must have a milestone dollar amount.	12/30/2022	$50,000		$50,000
Total				**$2,075,240**	**$1,124,742**	**$3,199,982**
			Period of Performance	**XX Months**		
			Agreement Type	**CPFF/CR/FFP**		

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. Invoicing should be monthly.
3. Monthly and Annual Reports include BOTH Technical Reports and Business Status Reports (separate).
4. Final Report due date must be prior to POP end noted in Research Project Award and have an associated milestone dollar amount.
5. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
6. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

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

- Monthly Reports – The MTEC research project awardee shall prepare a Quarterly Monthly Report which will include both a Technical Report and Business Expense Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

- Annual Reports – The project awardee shall prepare an Annual Report which will include both a Technical Report and Business Status 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. As part of the Final Technical Report, the awardee must submit a DD Form 882, Report of Inventions and Subcontracts. (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)

Addendum 2 – Stage 2 Evaluation Criteria

For Information Only - Stage 2 Requirement (subject to change)

Stage 2

The MTEC Consortium Manager (CM) will evaluate the cost proposed together with all supporting information for realism (as applicable, dependent upon contract type, i.e., Firm Fixed Price, Cost Reimbursement), reasonableness, and completeness as outlined below. The MTEC CM will then provide a formal assessment to the Government at which time the Government will make the final determination that the negotiated project cost is fair and reasonable.

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 technical approach and Statement of Work.

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 (Enhanced White Papers) 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, in its nature and amount, 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 based upon verifiable techniques such as estimates developed from applicable and relevant 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. If the MTEC template is not used, the Offeror should submit a format providing for a similar level of detail.

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.

Government Access to Information
After receipt of the cost proposal and after the CM's completion of the cost analysis summarized above, the government may perform a supplemental cost and/or price analysis of the submitted cost proposal. For purposes of this analysis, the Agreement Officer and/or a representative of the Agreement Officer (e.g., DCAA, DCMA, etc.) shall have the right to examine the supporting records and/or request additional information, as needed.

Best Value
The overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.