Request for Project Proposals

Solicitation Number: MTEC-22-03-Diarrheal

"Development of Oral Immunotherapy for the Prevention of Bacterial Diarrheal Disease"

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: December 21, 2021

Enhanced White Paper Due Date: February 7, 2022
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 prototypes with USAMRDC. 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 support of the DoD USAMRDC Military Infectious Diseases Research Program (MIDRP). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. Strategic oversight for the award(s) supported by this RPP will be provided by the MIDRP.

This RPP is focused on the development of a self-administered oral immunotherapy (not a vaccine) to prevent endemic diarrheal disease by targeting multiple bacterial pathogens. The self-administered oral immunotherapy should mitigate symptoms, shorten the duration of illness, and/or reduce the risk of contracting bacterial diarrheal illnesses. The proposed immunotherapy product would target enterotoxigenic *Escherichia coli* (ETEC), and at least one other common bacterial diarrheal pathogen such as *Campylobacter* or *Shigella*. The oral immunotherapy must be stable without requiring a cold-chain and therefore could be utilized by the Warfighter in austere environments.

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 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 available a total of approximately **$4.0 million (M)** for this effort. Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made under the authority of 10 U.S.C. § 2371b.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

It is expected that MTEC will make **up to two awards** to qualified Offerors in Fiscal Year (FY) 2022 to accomplish the scope of work. Note, however, that the Government reserves the right to make final evaluation and award decisions based upon, among other factors, programmatic relevancy and overall best value solutions determined to be in the Government's best interest. Therefore, if a single Enhanced White Paper is unable to sufficiently address the entire scope of this RPP's technical and regulatory requirements (outlined in Section 3), 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.

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

The Period of Performance (PoP) is **not to exceed four (4) years**.

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.6. for additional details.

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.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, current MTEC members 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 submitted and will select those that best meet their current technology priorities using the 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. § 2371b 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.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within three (3) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.5. Proprietary Information

The MTEC CM will oversee submission of Enhanced White Papers 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. **In accordance with the Proposal Preparation Guide (PPG), 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 (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, 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. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Enhanced White Paper submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government.

MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, Research and Development (R&D) highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.

- "Solicitation Collaboration Interests" - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regard to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit an Enhanced White Paper. Offerors submitting Enhanced White Papers as **the prime performer must be MTEC members of good standing at least 3 days prior to submission of the Enhanced White Papers**. 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/.

2.8. 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 the **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.).

2.9. Cost Sharing Requirements

In order to be compliant with 10 U.S.C. §2371b, 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**. Beyond that, cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see the **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 the **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award.

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 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. Awardees are not allowed to use MTEC funding to pay for their assessment fees. 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".

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant Research Project Award. 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 defined in the Base Agreement regarding IP and Data Rights**. It is anticipated that anything created under this proposed effort would be delivered to the Government with Unlimited Data Rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data shall be determined in accordance with the provisions of the MTEC Base Agreement.

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. For more information, the CM has published a resource for Offerors entitled, "Understanding Intellectual Property and Data Rights" on the MTEC members-only website.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning June 27, 2022 (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.

2.13. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward their 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

The mission of the MIDRP is to plan, coordinate and oversee for the DoD requirements-driven medical solutions that PREVENT, PREDICT, and TREAT infectious disease threats to the total force, maximizing Warfighter readiness and performance. The vision of the MIDRP is to defeat infection: prevent and/or treat naturally occurring infectious disease threats to eliminate their impacts on operational readiness of DoD personnel. MIDRP's Endemic Diarrheal Diseases research program focuses on non-vaccine prophylactics for the prevention of endemic diarrheal diseases, with a focus on bacterial diarrheal diseases.

Past conflicts demonstrate that endemic diarrheal diseases contribute to significant morbidity, high logistical burden for care, and combat ineffectiveness. Acute episodes of diarrheal diseases remain a leading cause of lost-duty days and deployment hospitalizations. Deployment-related endemic diarrheal diseases continue to pose a challenge to maintaining an operationally ready and capable Joint Force in future conflicts and consistently ranks as a top infectious disease threat to military operations.

Bacterial pathogens endemic to overseas locations account for the majority of diarrheal diseases in military populations. The DoD currently lacks the ability to prevent endemic diarrheal diseases to counter the impacts of illness and performance degradation in Warfighters. In addition to diarrhea, illnesses caused by these pathogens can result in vomiting, dehydration, and other debilitating symptoms for several days or more. The most prevalent bacterial pathogens are enterotoxigenic *E. coli* (ETEC), *Campylobacter*, and *Shigella*. Despite having controlled food and water distribution practices among which military populations operate, studies have found that diarrheal illness still occurs making prevention and treatment a high priority to Combatant Commands (COCOM).

Prevention, rather than treatment, is desirable to minimize lost duty days and possible sequelae following infection. To effectively prevent infectious diarrhea in the deployed setting, the U.S. military needs products and technologies that adequately address a medical syndrome caused by a wide variety of pathogen species and types. "Off-label" use of antibiotic prophylaxis with licensed antibiotics has been available for decades but is generally discouraged by medical authorities due to concerns over antimicrobial resistance as well as adverse effects from the antibiotics themselves. At this time, there is no licensed vaccine for the prevention of endemic diarrheal disease. Currently, there are no U.S. Food and Drug Administration (FDA) approved prophylactics available for use in the United States for a travelers' diarrhea indication. Therefore, the development of an oral immunotherapeutic to prevent travelers' diarrhea caused by endemic diarrheal pathogens is a priority for the MIDRP.

3.2. Expected Attributes/Capabilities for Submission of an Enhanced White Paper

Enhanced White Papers submitted in response to this RPP are expected to meet the following:

1. Minimum Technology Readiness Level (TRL): The expected TRL **at the time of submission of the Enhanced White Paper** is at least TRL 4 and, at the end of the PoP, TRL 6/7. Full definitions of TRLs can be found here.

2. Prototype/Product Solution: At the time of submission, the Offeror is expected to have a prototype/product solution with data informing performance characteristics, valency and formulation, as well as pre-clinical study data (*in vitro*, toxicology, pre-clinical animal data, etc.) indicating safety and/or efficacy. The submission should demonstrate initial suitability of the prototype solution for further optimization and testing.

    - The Offeror should detail any known or possible contra-indications or interferences in the military population for the prototype/product solution.

    - The Offeror should, if data is available, detail dosing of the prototype/product to include time from dose to meal.

3. Manufacturing Feasibility: The Offeror is encouraged to demonstrate manufacturing feasibility of the prototype solution. A pathway to current good manufacturing practice (cGMP) production at commercial scale should be feasible within the proposed development timeline.

4. Target Product Profile (TPP): The Offered is encouraged to submit a completed TPP using the FDA Guidance for Industry and Review Staff Target Product Profile – *A Strategic Development Process Tool* for direction.

In addition to these expected attributes/capabilities, it is **strongly preferred** that Offerors have had at least one meeting with the FDA to discuss the regulatory strategy for their prototype. Official and Unofficial FDA meeting minutes should be submitted (see Addendum 1). Therefore,

proposals demonstrating evidence of the FDA engagement and/or a statement on intent to receive FDA licensure for a particular indication/commercialization strategy may receive a higher rating.

3.3. Regulatory Requirements

The overall goal of this RPP is to develop a self-administered oral immunotherapy as a prophylactic against bacterial diarrheal disease caused by multiple pathogens (including ETEC). By the end of the PoP, it is expected that the performer/Offeror will deliver/demonstrate completion of the following:

- GLP-compliant studies demonstrating acceptable safety and efficacy profile in relevant animal model(s), human dose equivalent, and route of administration as intended for human use.

- A completed Trial Master File (TMF) based on the Drug Information Association (DIA) TMF model. The TMF shall allow for remote review by the government throughout the award.

- Phase 1 and/or Phase 2 clinical trial data demonstrating adequate safety profile in optimized dose and schedule.

- An adequately defined, detailed regulatory pathway towards a Medical Device, Biologics License or New Drug Application, including (but not limited to) Phase 2 or Phase 3 study plans validated by formal communication with the FDA.

In addition, the Offeror must provide evidence that production is capable of scale up and available quantities of the product are adequate to support the remainder of clinical development. The oral immunotherapy product must have demonstrated stability and have a long shelf life for the potential to be used directly by the Warfighter in austere environments.

3.4. Scope of Work

An ideal solution would meet all of the following requirements (not listed in order of importance) **by the end of the proposed PoP.** Therefore, Offerors shall address within the proposal submission how and when each of these will be accomplished during the PoP.

[Note: Although Enhanced White Papers that propose to meet all of the product requirements outlined below are **preferred**, the Government may consider responses demonstrating only a portion of the final product attributes if the team's approach can address how the remaining requirements can be met over time. Therefore, it is expected that an Offeror's Enhanced White Paper will describe in detail what they plan to accomplish and how they plan to satisfy **all** of the product requirements either during the proposed PoP or beyond that period (Offerors should specify the projected timeline), as applicable.]

- An immunotherapy product in an oral formulation for delivery to the gut.

- An oral immunotherapy product that prevents diarrhea attributable to ETEC and ***one or more other pathogens*** with evidence that multiple pathogens are feasibly targeted.

- The oral immunotherapy product would be self-administered, before or during deployment, offering protection throughout a routine deployment period (6 weeks – 6 months). The requiring activity (or end user) seeks to minimize in-theater dosing. If it must be administered in the field, three doses per day is the maximum frequency sought. Demonstration of less than three doses per day is highly favorable. Requirements for administration and re-supply storage must be consistent with prolonged care in austere environments, where evacuation and logistics capabilities will be minimal.

- The oral immunotherapy product: (1) would have ease of use (administration, easy-open packaging, components, suspension needs), (2) be usable and efficacious in austere environment conditions (packaging should maintain integrity in wide temperature ranges between 0-45ºC, and in conditions of high and low humidity), (3) be small and lightweight without the need for additional logistic considerations, e.g., cold/warm storage, impact protection, additional supplies/products to enable use (for example – water based suspensions).

At the end of the PoP, the Offeror(s) is expected to have successfully achieved **all** the following milestones:

- Completed studies which refine and optimize the prototype immunotherapy to prevent endemic diarrheal disease:

    - Completed proof of concept efficacy studies, dose-dependent efficacy studies (studies to minimize dosing while maintaining efficacy); and

    - Completed Good Laboratory Practice (GLP) compliant studies demonstrating sufficient safety and efficacy profile in relevant animal model(s), human dose equivalent, and route of administration as intended for human use; and

    - Completed IND-enabling studies, including in vivo toxicity studies (if needed), human tissue cross reactivity studies, and stability studies

- A completed Phase 1 and/or Phase 2 clinical trial demonstrating adequate safety and preliminary efficacy profile against all target pathogens in optimized dose and schedule

- All completed clinical studies shall be reported in a Final Clinical Study Report following ICH E3 Structure and Content or its current iteration.

- Evidence that production is capable of scale up and available quantities of the product are adequate to support the remainder of clinical development

- Demonstrated stability of product(s) for at least one year at 0-45ºC and under conditions of low and high humidity. Offerors should put accelerated conditions in their stability protocol to demonstrate limits of the technology

- A defined regulatory pathway: An adequately defined, detailed regulatory pathway towards a Medical Device, Biologics License or New Drug Application, including (but not limited to) Phase 2 and/or Phase 3 study plans validated by formal communication with the FDA.

3.5. Additional Points of Consideration

Within the Enhanced White Paper, offerors must identify and describe any existing/previous industry or DoD partnerships. The Offeror must describe the role each partner had in existing/previous projects (including any resultant contracts/grants/awards and/or IP). Partnership with industry or the USG/DoD is not a requirement for award but must be identified. See Section 8 for guidance on addressing this information in the Enhanced White Paper submission.

3.6. 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.

Offerors are encouraged, as appropriate, to discuss potential follow-on work in the Enhanced White Paper submission to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential capabilities that can be explored/achieved through short term and/or long-term advancement of the project in a way that is beneficial to the Government.

3.7. Restrictions on Animal and 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 Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review

Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

Enhanced White Papers must comply with the above-mentioned restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local IACUC and IRB approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the USAMRDC Animal Care and Use and Review Office (ACURO) and the USAMRDC HRPO. Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Proposal, as applicable.

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 USAMRDC HRPO provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO 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.

3.8. Guidance Related to DoD-Affiliated Personnel for Participation

Compensation to DoD-affiliated personnel for participation:
Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction (DODI) 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research. You may access a full version of the DODI by accessing this link: https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

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 Enhanced White Paper format provided in this MTEC RPP is **mandatory** and shall reference this RPP number (**MTEC-22-03-Diarrheal**). 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 in response to this RPP shall prepare all documents in accordance with the following instructions:

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, searchable, 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.

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 (6): Submitted via BIDS (5MB or lower per document)

- **Enhanced White Paper:** one PDF document
- **Warranties and Representations:** one Word or PDF document (**Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**Attachment 4 of the PPG**)
- **Current and Pending Support:** one Word or PDF document (**Attachment 5 of the PPG**)
- **Intellectual Property and Data Rights Assertions:** one Word or PDF document (**Attachment 6 of the PPG**)
- **FDA Meeting Minutes:** one Word or PDF document (**Addendum 1 of this RPP**)

Page Limitation: The Enhanced White Paper is limited to eleven (11) pages (including cover page). The following Appendices are **excluded** from the page limitation: *(1) Warranties and Representations, (2) Statement of Work, (3) Current and Pending Support, (4) Intellectual Property and Data Rights, and (5) Addendum for FDA Meeting Minutes.*

The Enhanced White Paper and its Appendices must be in 12-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables but must be clearly legible. 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 selected 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 to include the following:

- **Human Subject Recruitment and Safety Procedures** which details study population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, etc.
- **Letter(s) of Support**, as applicable, if the prototype project will require access to active-duty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix is 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 2.13).

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 as one Word or PDF document.**
- **Section II: Cost Proposal Formats as one Excel or PDF 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) or PDF file for **Section I: Cost Proposal Narrative** (the MTEC PPG will be provided by MTEC to Offerors invited to Stage 2). Separately, **Section II: Cost Proposal Formats** in either Excel (.xlsx or .xls) or PDF format is required.

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 in the MTEC website and within the PPG 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 considered a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not considered 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 PPG.

4.6. Telecommunications and Video Surveillance

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. For more information, please refer to Section 6.1.2 of the PPG.

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 Enhanced White Papers 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 distribute 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 stated source selection criteria and evaluation factors. 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.

Evaluation Factors

1. **Scientific Plan**
2. **Programmatic Relevance**
3. **Regulatory and Commercial Plan**

Evaluation Factor 1 – Scientific Plan:
This factor will evaluate the relevancy, thoroughness, completeness, and feasibility of the proposed approach (e.g., the technical merit) and how well the proposal defines and describes a prototype that can already meet or be modified to meet the attributes and requirements described in this RPP. The following will be considered:

- Hypothesis and objectives
- Scientific rationale with supporting preliminary data
- Scientific study design and feasibility, including the design of GLP-compliant studies in relevant animal model(s) and Phase 1 and/or Phase 2 clinical trials
- How well the Enhanced White Paper defines and describes a prototype that can meet the expected attributes/capabilities and technical requirements as set forth in this RPP under Section 3.
- The Government may consider the SOW and estimated budget as an aspect of overall Scientific Plan.
- The Government may consider the Offeror's discussion of potential follow-on work as a component of the Scientific Plan.

Evaluation Factor 2 – Programmatic Relevance:
This factor will evaluate how well the proposed prototype demonstrates alignment and relevancy with the program objectives and overall intent of the RPP as described in Section 3. This factor will also evaluate whether the potential immediate and long-range outcome(s)/product(s) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care. The Government may also consider the project management plan and experience of personnel as an aspect of overall programmatic relevance.

Evaluation Factor 3 – Regulatory and Commercial Plan:
This factor will evaluate the soundness and feasibility of the Offeror's regulatory strategy, including FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. Additionally, the feasibility of the commercialization strategy will be evaluated, including the degree to which the Offeror demonstrates potential commercial use, including a description of the market (civilian and military) and sustainability. The following will be considered:

- **Product Development and Regulatory Strategy:** The feasibility of the Offeror's regulatory strategy as validated by formal communication with the FDA, including FDA pathway, indication of use and designation, and strategy for obtaining FDA approvals or clearances. Included within this evaluation factor are the Offeror's target product profile (TPP), plan

to implement a TMF to allow remote review by the Government throughout the award, and pathway to cGMP production at commercial scale as described in Section 3.

- **Market and Business Model:** Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability. The Government may consider previous/existing partnerships as an aspect of the overall Regulatory and Commercial Plan.

Table 2 explains the adjectival merit ratings that will be used for the Scientific Plan, Programmatic Relevance, and Regulatory and Commercial Plan 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)***

The RPP review and award process may involve the use of contractor subject matter experts (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 Biomedical Research Associate, Dr. Gage Greening, Ph.D., gage.greening@mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
ATI	Advanced Technology International
CAS	Cost Accounting Standards
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
CMA	Consortium Member Agreement

COCOM	Combatant Command
DIA	Drug Information Association
DoD	Department of Defense
DODI	Department of Defense Instruction
EC	Ethics Committee
ETEC	Enterotoxigenic *E. coli* (ETEC)
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
GLP	Good Laboratory Practice
Government	U.S. Government, specifically the DoD
HRPO	U.S. Army Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MHS	Military Health System
MIDRP	Military Infectious Diseases Research Program
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Act
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
ORP	USAMRDC Office of Research Protections
OTA	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
PoP	Period of performance
PPG	Proposal Preparation Guide
R&D	Research and Development
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TMF	Trial Master File
TPP	Target Product Portfolio
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government

8 Enhanced White Paper Template

Cover Page

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

DUNS #: [DUNS #]
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 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 and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Enhanced White Paper and negotiate any subsequent award. 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]

Minimum Expected Attributes/Capabilities

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the needs specified in this RPP.
- Please indicate the TRL stage of the proposed solution at the time of submission of the Enhanced White Paper, as well as anticipated TRL at project completion. Full definitions of TRLs can be found here.

  TRL at Time of Submission:
  TRL at Project End:

Scope Statement

- Define the scope of the effort and clearly state the hypothesis and objectives of the project.

Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support the feasibility of proposed work.
- Describe relevant non-clinical data and/or clinical preliminary data.
- Describe your demonstration of the manufacturing feasibility of the prototype.

Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.
- Describe GLP-compliant studies demonstrating acceptable safety and efficacy profile in relevant animal model(s), human dose equivalent, and route of administration as intended for human use.
- Clinical Research and Trials (if applicable): Clinical trials (Phase I and/or Phase 2) should be described in adequate detail to assess conformance with IRB/HRPO and FDA regulations, guidance, and the requirements related to its appropriate pathway for development and testing.
  - Provide a description of the purpose and objectives of the study.
  - Provide a clear strategy for enrollment and attrition to include applicable risks and mitigation strategies.
  - Include a description of study variables, appropriate controls and the endpoints to be tested.
  - Outline the proposed methodology (e.g., study design, data analysis, etc.) in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.

- Describe current status of interactions with the U.S. Food and Drug Administration and your plan to meet all regulatory sponsor responsibilities.

Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have, if successful.

Potential Follow-On Work

Offerors are encouraged to keep this section to no more than one (1) page.

- [As noted in Section 3.6 of the RPP, additional follow-on funding may become available for the continuation of prototype development. Offerors are encouraged as appropriate to discuss potential follow-on work to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential capabilities that can be explored/achieved through short-term and/or long-term advancement of the project in a way that is beneficial to the Government. Although awards in response to this RPP may initially focus on the scope of work presented above, this section is intended to provide the Sponsor with information on the Offeror's plan for work beyond the initial proposed PoP.]
- Specify the objective and estimated cost of each proposed follow-on task.
- Briefly outline the proposed methodology **by task** to the extent possible.
- Indicate the proposed PoP (duration) for the potential follow-on work in total.

Technical and Management Team

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
- Describe the overall project management plan that clearly defines roles and responsibilities. This plan should include a communication and conflict resolution plan if the proposal involves more than one company/institution/organization.
- Describe the ability of the management team to advance the technology toward later TRLs beyond the scope of the proposed work described in the Enhanced White Paper.

Resources

- Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

Market and Business Model

- Clearly articulate the value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

Product Development and Regulatory Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).
- Describe previous interactions with the FDA related to this proposed prototype solution (e.g., pre-submission meeting).
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Describe plan to implement a TMF based on the DIA TMF model.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.
- If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.
- Clearly describe previous/existing partnerships with industry or the USG/DoD (including any resultant contracts/grants/awards and/or IP).

Schedule

- PoP: Indicate the proposed PoP in months from award.
- Proposed Schedule: Provide a schedule (e.g., Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task (to include regulatory-specific tasks) as a separate line. Do not duplicate the level of detail presented in Appendix 1.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

Rough Order Magnitude (ROM) Pricing

- The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper. The following ROM pricing example format shall be included in the Enhanced White Paper (the number of columns should reflect the proposed PoP, i.e., add or delete the yearly budget columns as needed). **[NOTE: If invited to Stage 2, the total cost to the Government must not significantly increase from the estimate provided in the ROM (unless otherwise directed by the Government) as award recommendations may be based upon proposed costs within the Enhanced White Paper.] Use the example table format and template below to provide the ROM pricing.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table. If selected for award, a full cost proposal will be requested.

	Year 1	***Year 2***	***Year 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*	*$ 100,000.00*	***$ 300,000.00***
Labor Hours	*1,000.0 hrs*	*1,000.0 hrs*	*1,000.0 hrs*	***3,000.0 hrs***
Subcontractors	*$ 50,000.00*	*$ 50,000.00*	*$ 50,000.00*	***$ 150,000.00***
Subcontractors Hours	*500.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	*$0.00*	*$0.00*	*$0.00*	***$0.00***
Gov't/Military Prtnrs / subKTR Hours	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	***0.0 hrs***
Consultants	*$ 10,000.00*	*$ 10,000.00*		***$ 30,000.00***
Consultants Hours	*100.0 hrs*		*0.0 hrs*	***300.0 hrs***
Material/Equipment	*$ 75,000.00*		*$ 75,000.00*	***$ 225,000.00***
Other Direct Costs		*$ 1,000.00*	*$ 1,000.00*	***$ 3,000.00***
Travel	*$ 5,000.00*	*$ 5,000.00*	*$ 5,000.00*	***$ 15,000.00***
Indirect costs	*$ 48,200.00*	*$ 48,200.00*	*$ 48,200.00*	***$ 144,600.00***
Total Cost	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	***$ 867,600.00***
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*	*$ 0.00*	*$ 0.00*	***$ 0.00***
Total Cost (plus Fee)	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	***$ 867,600.00***
Cost Share (if cost share is proposed then fee is unallowable)	*$ 290,000.00*	*$ 290,000.00*	*$ 290,000.00*	***$ 870,000.00***
Total Project Cost	*$ 579,200.00*	*$ 579,200.00*	*$ 579,200.00*	***$ 1,737,600.00***

EXAMPLE

*Use the rows above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

Estimate Rationale

- 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 Attachment 4 of the PPG)

- Provide a draft Statement of Work as a separate 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: Current and Pending Support (template provided in Attachment 5 of the PPG)

- The Offeror shall provide this information for all key personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and non-government), including the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), role, brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap. If there is no current and/or pending support, enter "None."

Appendix 4: Data Rights Assertions (template provided in Attachment 6 of the PPG)

- 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 Unlimited Data Rights unless otherwise asserted in the proposal and agreed to by the Government.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables/milestones. If applicable, complete the table within the referenced attachment for any items to be furnished to the Government with restrictions.

Appendix 5: FDA Meeting Minutes (template provided in Addendum 1 of this RPP)

- It is strongly preferred that Offerors have had at least one meeting with the FDA to discuss the regulatory strategy for their prototype. In order to address this within the proposal submission, the Offeror should provide documentation of official and unofficial meeting minutes with the FDA (uploaded as a separate document). If there are no meeting meetings to provide, this appendix must still be submitted with the appropriate box checked.

Addendum 1 – FDA Meeting Minutes

It is strongly preferred that Offerors have had at least one meeting with the FDA to discuss the regulatory strategy for their prototype.

Directions to the Offeror

The Offeror shall check one of the boxes below. All Offerors shall upload this Addendum as a separate appendix with their proposal package (see Section 8 of this RPP). If the Offeror has met with the FDA, attach the meeting minutes, along with this page, as a single PDF.

Failure to provide this may result in removal from the competition and the proposal determined to be ineligible for award.

☐ If the Offeror WILL be submitting FDA meeting minutes, check this box.

☐ If the Offeror will NOT be submitting FDA meeting minutes, check this box.

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 Reimbursable), 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 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. 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.