

Request for Project Proposals



Solicitation Number: MTEC-22-10-ChemBio

“Algorithm Development for Early Warning and Prediction of Chemical and Biological Threat Exposure Leveraging Artificial Intelligence and Machine Learning (AI/ML) Approaches”

Issued by:
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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the 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 U.S. Defense Threat Reduction Agency (DTRA). Military relevance is a critical component of the Enhanced White Paper submission. Strategic oversight for the award(s) supported by this RPP will be provided by DTRA's Digital Battlespace Management Division (RD-CBI).

This RPP is focused on the development of a software prototype containing algorithm(s) for early warning of chemical and biological threats. The project will involve proof-of-concept algorithmic development for providing predictive values indicative of a potential exposure/infection to a chemical/biological threat prior to symptom onset by utilizing physiological data captured from wearable devices.

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) expects to have up to \$1.47 million (M) in Fiscal Year 2023 (FY23) for this program. Additional funding may be later available (if approved), under future appropriations, to the successful Offeror(s) to continue prototype development after project award. Award and funding from the Government is contingent upon the availability of federal funds for this program.

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 a **single award** to a qualified Offeror in FY23 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.

The Period of Performance (PoP) is **not to exceed 36 months/3 years**, dependent upon the maturity of the proposed solution.

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 3.4 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 funding will be 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. § 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.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) 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 and present further insight into the Technical Requirements outlined in Section 3. 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 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. **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. The following two resources may help prime contractors provide a more complete team for this requested scope of work.

2.6.1. MTEC M-Corps

The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning, cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction Advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls (CMC), clinical trials, concepts and requirements development, design development and verification, manufacturing, process validation, manufacturing transfer quality management, regulatory affairs]. Please visit <https://www.mtec-sc.org/m-corps/> for details on current partners of the M-Corps.

2.6.2. MTEC Database Collaboration Tool

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 **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 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**. 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 **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.

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. 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”.

2.11. Intellectual Property and Data Rights

Baseline 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 contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. Due to this project's unique requirements, the Government is identifying, in this RPP, the following level of specifically-negotiated IP and Data rights required by the Government for this project. The Awardee shall grant to and/or obtain for the Government, Government Purpose Rights to all Category A and Category B Data including all documents, software, and materials developed under this award, and those developed prior to award by the Awardee or other entity, which are needed for the purposes of cybersecurity assessments, software updates, upgrades and capability insertions for future enhancements of the project deliverables (this may include but is not limited to executables, source code, algorithms, associated scripts, build procedures, automation scripts, tools, databases, libraries, test results, data sets, firmware, and training materials). The documents, software, and materials developed under this award, as well as those developed prior to award as mentioned in the preceding sentence, shall be Offeror owned, with the Government receiving Government Purpose Rights therein. Any Commercial Computer Software and/or Data needed for the purposes herein described must be delivered with a commercial license granting to the Government rights equivalent to the Government Purpose Rights described herein. The documents, software and materials produced under the Award shall not be sold back to a different Government entity as the Government is receiving Government Purpose Rights therein. All documents, materials and software supplied to the Government under this Award shall be conveyable to other government entities and third parties within the limitations of a Government Purpose Rights license as mentioned above, with no notice to or authorization from the Offeror needed. This right does not abrogate any other Government rights. For purposes of this this section (i.e., paragraph 2.11), the terms "developed" and "government purpose" shall have the same definition as utilized in DFARS 252.227-7014.

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 March 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.

2.13. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward its selection(s) 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

Prior to the COVID-19 pandemic, DTRA's Digital Battlespace Management Division (RD-CBI) leveraged non-invasive physiological data to develop predictive algorithms capable of informing users of a potential exposure/infection to a chemical/biological threat prior to symptom onset. This capability was initially based on clinical hospital datasets that utilized hospital-grade monitoring devices. It was subsequently expanded to include multiple, large-scale, real-time datasets collected throughout the COVID-19 pandemic using commercial-off-the-shelf (COTS) devices. This capability illustrated the feasibility of an infection-based predictive algorithm built strictly from physiological data collected from wearable devices. The early warning capability is undergoing continued research and development (R&D), and has been refined to alert participating COTS device wearers and users to a potential COVID-19 exposure up to 48 hours in advance of symptom onset. Physiological data has been acquired from COTS devices such as the Garmin Fenix 6 smartwatch, Oura ring (Generation 2 and 3 versions), Dexcom patch (G6 Pro), Empatica E4 wristband, BioTel ePatch, among other devices and clinical ground truth data. Further R&D is underway to collect wearables-based, physiological data from over 10,000 participants for analysis and future algorithm development, including data verification and validation.

The objective of this RPP is to implement artificial intelligence/machine learning (AI/ML) methods and analytics approaches that can provide alerts of exposure to chemical and biological threats. Biological threats have been of interest due to the nature of incubation and transmission timelines; however, there is also interest in utilizing these methods to enhance capabilities for identifying chemical exposures through physiological-based data. Such improved capabilities would enhance the U.S. Department of Defense's (DoD) capacity to limit the spread of a contagious agent throughout the force and/or more rapidly implement mitigation measures (e.g., medical countermeasures, quarantine), thereby reducing overall morbidity and mortality and increasing force readiness.

3.2. Solution Requirements

DTRA's Digital Battlespace Management Division (RD-CBI) is seeking a performer who can leverage existing wearable device-based datasets to develop algorithms that have the following attributes (not listed in order of importance):

1. Produce a higher confidence predictive model for a biological and chemical threat exposure at lower than a 15% false positive rate
2. Be optimized for data degradation: lowest capture of data or fewest number of viable physiological features to still achieve the optimal false negative and low false positive rate
3. Provide an earlier prediction (i.e., greater than 48 hours) before symptom onset
4. Be threat agnostic, with the ability to alert to any potential biological and chemical exposure
5. Differentiate and account for confounding factors including but not limited to: sleep deprivation, exercise, activities at rest, and other daily stressors

3.3. Scope of Work

Although Enhanced White Papers that propose to meet all of the product attributes outlined in Section 3.2 are **preferred**, the Government may consider responses proposing to achieve only a portion of the final product attributes if the Offeror's approach can address how the remaining requirements can be met over time. Therefore, it is expected that an Offeror's Enhanced White Paper (using the template provided in Section 8 of the RPP) will describe in detail what they plan to accomplish within the budget currently available (as noted in Section 2.2). **Although the Government anticipates \$1.47M available in FY23, Offerors are encouraged to request only what is needed to accomplish the solution requirements.**

If the proposal is not able to fully address the envisioned solution within the \$1.47M of anticipated FY23 funding, the Offeror is expected to describe and provide a roadmap (using the template provided in **Addendum 2**) to achieve the envisioned end state during the proposed PoP (if more funding was available). If future appropriations (FY24+) become available, this roadmap may help inform future modifications to increase the funding of the awarded project(s) and add additional tasks to move closer to the Offeror(s)'s envisioned solution.

Offerors are encouraged to bring forth proposals that include teaming arrangements with other organizations to try to address all or as many of the attributes as possible (see Section 2.6 for teaming).

In the Enhanced White Paper, Offerors are expected to provide the following information in their submissions:

- Describe prior successful experience in AI/ML data analytics and algorithm development.
- Discuss the intended use of specific AI/ML approaches for advanced data analytics to achieve a high-fidelity solution leveraging the DTRA-provided datasets and existing datasets from the Offeror.

- The ability to apply AI/ML approaches is often contingent on high-quality data inputs, and thus can be difficult to develop a reliable algorithmic solution using AI/ML from wearable device-based data, which is often noisy and has long breaks in data points. Proposals should address the ability to overcome these challenges and methods by which AI/ML approaches can benefit algorithm development.
- Description of the types of AI/ML algorithms for medical purposes that will be developed in addition to any potential algorithms that could be developed and the types of data/amount of data necessary for developing those algorithms, as well as the strategy and feasibility of successfully developing each algorithm.
- Work conducted under this effort should comply with the DoD policies, guidance, and best practices referenced in **Addendum 3 of this RPP**.

At the end of the PoP, the Offeror is expected to deliver to the Government a Technical Data Package to include a software design description, computer software product (e.g., executables, source code, and algorithms), software test plan, and verification and validation support documentation.

3.4. 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.

3.5. 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. 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 OHRO regulatory review and approval processes.

Enhanced White Papers must comply with the above-mentioned restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local IRB approvals,

continuing review (in the intervals specified by the local IRB, but at a minimum, annually), and approval by the USAMRDC OHRO. Offerors shall include IRB and OHRO 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.

The USAMRDC OHRO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC OHRO 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 OHRO review and authorization process.

3.6. 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 Offeror shall include MTEC Solicitation Number (**MTEC-22-10-ChemBio**) 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 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 (5): 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**)
- **Intellectual Property and Data Rights Assertions:** one Word or PDF document (**Attachment 6 of the PPG**)
- **Technical Addendum for Follow-on Work:** one Word or PDF document (**Addendum 2 of this RPP**)

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following Appendices are **excluded** from the page limitation: (1) *Warranties and Representations*, (2) *Statement of Work*, (3) *Intellectual Property and Data Rights Assertions*, and (4) *Technical Addendum for Follow-on Work*.

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:** one Word or PDF document
- **Section II: Cost Proposal Formats:** one Excel or PDF document

See below for additional instructions. Also refer to **Addendum 1 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** and one Excel (.xlsx or .xls) or PDF file for **Section II: Cost Proposal Formats** 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 allowable as 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 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: <ul style="list-style-type: none">• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution |

| | |
|------|---|
| | <ul style="list-style-type: none"> • 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 | <p>Offeror proposing an MTEC research project does NOT meet at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research 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 |

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 in descending order of importance.

Evaluation Factors

- 1. Programmatic Relevance & Technical Feasibility**
- 2. Experience and Expertise**
- 3. Potential for Transition**

Evaluation Factor 1 – Programmatic Relevance & Technical Feasibility:

This factor will evaluate the relevancy, thoroughness, completeness, and feasibility of the proposed technical approach and strategy for analyzing data, developing the algorithm, and considering AI/ML technology. The Government will consider how well the proposal defines and describes a prototype that can meet the expected product attributes/capabilities and technical requirements set forth in this RPP as well as the scientific rationale and previous related work that supports the feasibility of the proposed work. The Government may consider the SOW and estimated budget as an aspect of overall Technical Feasibility. Therefore, comments addressing the Rough Order of Magnitude (ROM) describing the cost/price as “sufficient,” “insufficient,” or “excessive” may be provided. See Section 5.3. below for definitions of these terms.

Evaluation Factor 2 – Experience and Expertise:

This factor will evaluate the Offeror’s previous experience and expertise conducting large scale data analysis, algorithm development, and implementing AI/ML approaches. As part of this evaluation factor, the Government will also consider the project management plan, experience of proposed personnel, and the ability for the technical and management team to execute the proposed SOW in an efficient and effective manner. The Government will also consider whether the proposal includes a realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

Evaluation Factor 3 – Potential for Transition:

The Offeror’s proposal will be evaluated for its potential to transition the proposed prototype to the Government. This factor will assess whether the Offeror’s proposal complies with IP and data rights requirements detailed in Section 2.11 of the RPP for all documents, software, and materials, including the source codes, algorithms, libraries and additional files required to compile and run the software, developed under this award.

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 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.

The following terms may be used to evaluate the Rough Order of Magnitude (ROM) cost/price estimate:

Sufficient - The ROM estimate is within the available funding limits and considered appropriate to successfully complete the proposed project

Insufficient - The ROM estimate is lower than what is considered appropriate to successfully complete the proposed project

Excessive - The ROM estimate is higher than what is considered appropriate to successfully complete the proposed project

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

7 Acronyms/Abbreviations

| | |
|-------|--|
| AI/ML | Artificial Intelligence and Machine Learning |
| ASD | Application Security and Development |
| ATI | Advanced Technology International |
| CM | Consortium Manager |
| CMA | Consortium Member Agreement |
| CMC | Chemistry, Manufacturing, and Controls |
| COTS | Commercial off-the-shelf |
| DCAA | Defense Contract Audit Agency |
| DCMA | Defense Contract Management Agency |
| DoD | Department of Defense |
| DODI | Department of Defense Instruction |
| DTRA | Defense Threat Reduction Agency |
| EC | Ethics Committee |

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| | |
|------------|--|
| F&A | Facilities and Administrative Costs |
| FAQ | Frequently Asked Questions |
| FOIA | Freedom of Information Act |
| FY | Fiscal Year |
| G&A | General and Administrative Expenses |
| Government | U.S. Government, specifically the DoD |
| IA | Information Assurance |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| IT | Information Technology |
| IRB | Institutional Review Board |
| M | Millions |
| MPS | Milestone Payment Schedule |
| MTEC | Medical Technology Enterprise Consortium |
| NDA | Nondisclosure Agreement |
| OCI | Organizational Conflict of Interest |
| ODC | Other Direct Costs |
| OHARO | Office of Human and Animal Research Oversight |
| OHRO | Office of Human Research Oversight |
| 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 |
| RD-CBI | DTRA's Digital Battlespace Management Division |
| RMF | Risk Management Framework |
| ROM | Rough Order of Magnitude |
| RPA | Research Project Award |
| RPP | Request for Project Proposals |
| SISO | Senior Information Security Officer |
| SME | Subject Matter Expert |
| SOW | Statement of Work |
| STIG | Security Technical Implementation Guide |
| 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]

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 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]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Describe how the proposed technology meets the needs specified in this RPP.

Scope Statement

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

Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of previous related work data that supports the feasibility of proposed work.

Technical Approach

- Describe the design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action to address the solution requirements (Section 3.2) and required tasks (Section 3.3)
- This section should describe in detail what you plan to accomplish within the budget currently available (as noted in Section 2.2). Although the Government anticipates \$1.47M in FY23 funding, Offerors are encouraged to request only what is needed to accomplish the solution requirements.
- If the proposal is not able to fully address the envisioned solution within the \$1.47M of anticipated FY23 funding, the Offeror is expected to describe and provide a roadmap (using the template provided in **Addendum 2**) to achieve the envisioned end state during the proposed PoP (if more funding was available).

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, in supporting the goal of minimizing mission impact from chemical and biological threats.

Technical and Management Team

- Describe the qualifications and expertise of the proposed 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.

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.

Transition to the Government

- Describe the software deliverables and computational resources required for data processing and storage envisioned to support the final vision of the algorithm(s). Describe how this aligns with currently fielded capabilities at each echelon.
- 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 as a separate line. Do not duplicate the level of detail presented in the Statement of Work.

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.

| | <i>Year 1</i> | <i>Year 2</i> | <i>Year 3</i> | <i>TOTAL</i> |
|-----------------------------|----------------------|----------------------|----------------------|----------------------|
| Labor | <i>\$ 100,000.00</i> | <i>\$ 100,000.00</i> | <i>\$ 100,000.00</i> | <i>\$ 300,000.00</i> |
| Labor Hours | <i>1,000.0 hrs</i> | <i>1,000.0 hrs</i> | <i>1,000.0 hrs</i> | <i>3,000.0 hrs</i> |
| Subcontractors | <i>\$ 50,000.00</i> | <i>\$ 50,000.00</i> | <i>\$ 50,000.00</i> | <i>\$ 150,000.00</i> |
| Subcontractors Hours | <i>500.0 hrs</i> | <i>500.0 hrs</i> | <i>500.0 hrs</i> | <i>1,500.0 hrs</i> |

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| | | | | |
|---|---------------|---------------|---------------|-----------------|
| 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 | \$ 10,000.00 | \$ 30,000.00 |
| Consultants Hours | 100.0 hrs | 100.0 hrs | 100.0 hrs | 300.0 hrs |
| Material/Equipment | \$ 75,000.00 | \$ 75,000.00 | \$ 75,000.00 | \$ 225,000.00 |
| Other Direct Costs | \$ 1,000.00 | \$ 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 |

*Use the rows above for “Government/Military Partner(s)/Subcontractor(s)” if the project involves one or more Government/Military Facilities (Military Health System 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 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: 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 in accordance with Section 2.11 of the RPP 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.

Addendum 1 – 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 whether or not the negotiated project cost is fair and reasonable.

a) **Realism.** Proposals will be evaluated (for those that will result cost reimbursable type Research Project Awards) 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 represent what the cost of the project should be for the effort to be accomplished, assuming reasonable economy and efficiency. 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.

Addendum 2 – Technical Addendum for Follow-on Work

Stage 1 Required Document

General Instruction: As noted in Section 2.2 of the RPP, additional funding may be available for the performer(s) that is selected for the continuation of prototype development. If the proposal is not able to fully address the envisioned solution within the \$1.47M of anticipated FY23 funding, the Offeror is expected to describe and provide a roadmap (using the template provided in Addendum 2) to achieve the envisioned end state during the proposed PoP (if more funding was available). Although awards in response to this RPP will initially focus on the scope of work proposed in the Enhanced White Paper, this addendum is intended to provide the Sponsor with information on the Offeror’s plan for work required to complete the prototype. The following template must be uploaded in BIDS as part of the Stage 1 requirement. **This addendum has a 2-page limit.**

If this Addendum is not applicable to a particular Offeror’s submission, please upload a document that states, “Our Enhanced White Paper proposes a plan to satisfy all of the solution requirements described in Section 3.2 within the available funding described in Section 2.2. No additional detail is required to be presented in this addendum.”

Technical Tasks: [Specify the objective of each proposed follow-on task. Outline the proposed methodology to the extent possible to demonstrate a course of action that addresses the complete solution requirements described in this RPP.]

PoP: [Indicate the proposed PoP (duration) for the potential follow-on work in total. The Government expects that the entire effort for the proposed project would not exceed 3 years.]

Gantt Chart: [Include a Gantt chart that demonstrates the timeline for each proposed potential follow-on task.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed follow-on work. List milestones and deliverables from the proposed follow-on work.]

Participants: [If different from those described in the Enhanced White Paper, briefly state the qualifications of any additional expertise, organizations, etc. that will be required to perform the proposed follow-on tasks.]

Rough Order of Magnitude (ROM) Pricing:

[Indicate the ROM pricing (including indirect costs) **using the table format below**. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project. The labor, travel, material costs, other

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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.]

| | Year 1 | Year 2 | Year 3 | Total |
|--|----------------|----------------|----------------|----------------|
| Labor | \$200,000.00 | \$200,000.00 | \$200,000.00 | \$600,000.00 |
| Subcontractors | \$100,000.00 | \$100,000.00 | \$100,000.00 | \$300,000.00 |
| Consultants | \$20,000.00 | \$20,000.00 | \$20,000.00 | \$60,000.00 |
| Material/Equipment | \$150,000.00 | \$150,000.00 | \$150,000.00 | \$450,000.00 |
| Other Direct Costs | \$2,000.00 | \$2,000.00 | \$2,000.00 | \$6,000.00 |
| Travel | \$10,000.00 | \$10,000.00 | \$10,000.00 | \$30,000.00 |
| Indirect Costs | \$96,400.00 | \$96,400.00 | \$96,400.00 | \$289,200.00 |
| Fee (not applicable if cost share is proposed) | | \$0 | \$0 | \$0 |
| Total Cost (plus Fee) | \$578,400.00 | \$578,400.00 | \$578,400.00 | \$1,735,200.00 |
| Cost Share (if cost share is proposed then fee is un-allowable) | \$580,000.00 | \$580,000.00 | \$580,000.00 | \$1,740,000.00 |
| Total Project Cost | \$1,158,400.00 | \$1,158,400.00 | \$1,158,400.00 | \$3,475,200.00 |

Addendum 3 – Software Development Guidelines

Under the resultant award, the performer must ensure configurations and installations are designed to meet the Cybersecurity requirements set forth in [DoDI 8500.1, Incorporating Change 1, Effective October 7, 2019](#) (current version). Cybersecurity implementations must be certified in accordance with [DoDI 8510.01](#) (current version).

Installation of software deliverables within a DTRA pre-production or software development or lab environment is contingent upon Senior Information Security Officer (SISO) review and approval of the controls used to isolate the test or evaluation instance from DTRA's operational networks and dependent upon the controls proposed, may require software code analysis.

Work conducted under this effort must be in alignment with the following DoD policies:

- DoDI 8500.1 Cybersecurity, Incorporating Change 1, 7 October 2019
- DoDI 8510.01 Risk Management Framework (RMF) for DoD Information Technology (IT), Incorporating Change 3, 29 December 2020
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