Request for Project Proposals

Solicitation Number: MTEC-24-01-MPAI

"Fiscal Year 2024 Military Prototype Advancement Initiative (MPAI)"

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: October 5, 2023
Amendment No. 01 Issue Date: December 11, 2023
Amendment No. 02 Issue Date: January 3, 2024

Enhanced White Paper Due Date: January 22, 2024
Noon Eastern Time Zone

Amendment No. 01 does the following:
Revises Section 4.2 to add Current and Pending Support as a required submission document for all Focus Areas.
Replaces Addendum 4 – Current and Pending Support template in its entirety.

Amendment No. 02 does the following:
Extends the proposal due date from January 15, 2024 to January 22, 2024.
All other terms and conditions remain unchanged.

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 openly recruiting members to join 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 OTA Guide dated July 2023, 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) to solicit current MTEC members for a broad range of medical prototype technological and knowledge solutions related to the Focus Areas of Interest (also called "Focus Area(s)") listed below. Proposed solutions may

include medical techniques, knowledge products, and materiel[1] (medical devices, drugs, and biologics). Military relevance is a key feature of this RPP, especially is it relates to the USAMRDC's Combat Casualty Care Research Program (CCCRP), Military Infectious Diseases Research Program (MIDRP), and Military Operational Medicine Research Program (MOMRP), as well as the U.S. Air Force School of Aerospace Medicine.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC, in partnership with the Government, is once again utilizing a streamlined solicitation approach for the Military Prototype Advancement Initiative (MPAI), a broad, multiple focus area RPP aimed at soliciting for and funding a wide range of projects of varying scope and maturity levels. This approach has been shown to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. This solicitation mechanism also includes several unique features, noted below:

- *Increase information exchange between the MTEC membership and the military* – This solicitation mechanism provides the MTEC membership with an official way of sending information related to their military-relevant solutions through MTEC to the military, and potentially make the military aware of new solutions that can address unmet needs.

- *Provide feedback to the MTEC membership* –MTEC membership will receive feedback from the Government, which can help Offerors realign to better meet the Government/military need downstream, or even find out whether the Government/military would be interested at all (a "not interested" is valuable feedback as well). Having said that, due to the anticipated high number of submissions and the need for a compressed timeline for the review cycles, feedback provided may be **VERY BRIEF.** Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback. To supplement these succinct reviews, MTEC has implemented an educational webinar series and through this, hopes to offer opportunities throughout the year for MTEC members to hear from and interact with the military Sponsors. While this will not allow for direct and specific feedback on Offerors' proposals, it will allow for an open discussion regarding priorities and capability gaps within the Government's portfolios.

- *Establish an open window for the military to make awards* – The solicitation mechanism is intended to provide MTEC members with an opportunity to propose solutions throughout the year. Offerors are advised that updates may be added via amendment at any time to reflect changes in Government requirements or other revisions, as

[1] Materiel is defined as equipment and supplies of a military force.

appropriate. With an extended open submission period, awards may be made on a first-in, first-out basis. Additionally, the MTEC selection process for this solicitation includes a "basket" provision that permits holding proposed projects that have technical merit, but unfunded, for up to two years, which allows for efficient contracting as funding becomes available.

- *Solicit for key areas to support achievement of the USAMRDC strategic objectives* – The Focus Areas of Interest will allow MTEC members to propose innovative and relevant solutions to USAMRDC's current medical needs.

- *Diversity in potential Sponsors* – While USAMRDC is listed throughout this RPP, sponsoring offices from outside commands (such as the U.S. Air Force) may also participate in the source selection process and select projects for award depending on interest, programmatic alignment, and funding availability.

The Enhanced White Paper process used for this effort 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 (see Section 4.1 for details on the submission period). *Enhanced White Papers may not be considered under this RPP unless* received on or before the due date specified on the cover page.

Each 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 (PoP)

The funding amount and PoP for this RPP is unspecified, and the number of awards is indeterminate and contingent upon funding availability. Selection of prototype projects is a highly competitive process and is based on the evaluation of the proposal's technical merit, programmatic considerations (to include program portfolio composition), and the availability of funds. The quantity of meaningful submissions received normally exceeds the number of awards that the available funding can support. Any funding that is received by the USAMRDC and is appropriate for a Focus Area of Interest described within this RPP may be utilized to fund

Enhanced White Papers. Awards resulting from this RPP are expected to be made in FY 2024 and 2025 under the authority of 10 U.S.C. § 4022.

A proposed budget and PoP should be commensurate with the nature, scope and complexity of the proposed research. Offerors should submit budgets that include the entire PoP of the research project. Yearly budgets should include all direct and indirect costs, based on supportable, verifiable estimates. Offerors are encouraged to scope out their budgets in alignment with major deliverables of their proposed work so that large budgets are easier to evaluate, and Sponsors can more easily allocate available funding.

For informational purposes, the average size of MTEC awards for the initial PoP is approximately $2.0 – 3.5M over a 2-3-year PoP unless otherwise specified in Section 3.

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).

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

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

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 intends to host a Proposers Conference that will be conducted via webinar within several weeks of the release of the RPP and may include multiple sessions as deemed appropriate. Further instructions will be forthcoming via email. The intent of the MPAI Proposers Conference series is to provide an administrative overview of this RPP process to award and to present further insight into the Focus Areas of Interest outlined in Section 3. 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 information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Enhanced White Paper and the subsequent agreement administration if the Proposal is selected for award. **In accordance with the MTEC 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 contacts private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors who are granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research

project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.6. 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 resources may help prime contractors provide a more complete team for this requested scope of work.

2.6.1. MTEC Member Connect

MTEC intends to host a series of virtual "connect" session via webinar to help the membership collaborate and partner in relation to 24-01-MPAI RPP. Each organization will be allotted 1 minute to pitch accompanied by a slide. Your pitch can be focused on whatever you think would be most beneficial to you in relation to your work, for example, seeking a partner or offering a capability. There will be contact info on each slide so that you can follow-up directly with whomever you would like.

2.6.2. 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 advice], and technical expertise [i.e., chemistry, manufacturing and controls, 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.

2.6.3. MTEC Database Collaboration Tool

MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. The Database Collaboration Tool provides a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. 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 (https://private.mtec-sc.org/).

2.6.4. Chat Forum

A dedicated chat forum has been established to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. The chat forum can be accessed via the "Discuss Portal" on the MTEC members-only website - https://private.mtec-sc.org/.

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. Statutory Requirements for the Appropriate Use of Other Transaction Authority

Enhanced White Papers that do not include one of the following will not be eligible for award (**See Section 3 of the PPG)**:

(A) At least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project; or

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

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

2.9. 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 PGG** 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.).

2.10. Cost Share Requirements

In order to be compliant with 10 U.S.C. §4022, 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.

2.11. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement, each recipient of an RPA under the MTEC OTA shall pay MTEC an amount equal to 2.0% of the total funded value of each research project awarded. Such deposits shall be due no later than 90 days after the RPA 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".

2.12. Intellectual Property and Data Rights

Baseline IP and Data Rights for the MTEC RPA are defined in the terms of an awardee's Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant RPA. 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. **It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each RPA shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of 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)** with the Signature of the responsible party for the proposing Prime Offeror.

2.13. Expected Award Date

Offeror should plan on the PoP beginning no sooner than 4 months after the submission deadline (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing an RPA.

2.14. 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

Current wartime operations assume that the United States and our allies will maintain air, land, maritime, space and cyber superiority. Future conflicts against peer and near-peer adversaries are expected to be layered stand-offs and fought across multiple domains. Mission success will be determined by our ability to compete to expand the competitive space, penetrate both strategically and operationally, disintegrate enemy's defenses, exploit enemy weaknesses, and re-compete to consolidate gains. Medical capabilities play a critical role in each aspect of the future battlespace and must modernize rapidly to maintain Force readiness and increase soldier lethality.

3.2. Minimum Requirements for Submission of an Enhanced White Paper

Enhanced White Papers submitted in response to this RPP shall meet the following minimum requirements:

1. Demonstrate Military Relevance: Proposed projects shall focus on providing medical solutions to support readiness and care in future battlefield scenarios.

2. Fit the Prototype Definition: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. The definition of a "prototype" is as follows: (A) a prototype project addresses a proof of concept, model, (B) reverse engineering to address obsolescence, (C) a pilot, novel application of commercial technologies for defense purposes, (D) agile development activity, (E) the creation, design, development, demonstration of technical or operational utility, or (F) combinations of the foregoing. A process, including a business process, may be the subject of a prototype project.

3. Meet the Minimum Knowledge/Technology Readiness Level (KRL/TRL): The minimum acceptable KRL/TRL **at the time of submission of the Enhanced White Paper** is at least KRL/TRL 3 for most of the focus areas listed herein. Offerors have achieved KRL/TRL 3 if:

    - **Knowledge Products:** Offeror has validated hypotheses that suggest applications (e.g., prediction for prognosis, screening for diagnosis, or treatment for prevention)
    - **Pharmaceutical (Drugs):** Offeror has demonstrated initial proof-of-concept for candidate drug constructs in a limited number of in vitro and in vivo research models
    - **Pharmaceutical (Biologics, Vaccines):** Offeror has demonstrated initial proof-of-concept for biologic/vaccine constructs in a limited number of in vitro and in vivo research models.
    - **Medical Devices:** Offeror has demonstrated initial proof-of-concept for device candidates in a limited number of laboratory models (may include animal studies).

- **Medical Information Management (IM)/Information Technology (IT) & Medical Informatics:** Medical Informatics data and knowledge representation schema are modeled.

Offerors should note that all topics within Focus Areas 1 (Combat Casualty Care), as well as Focus Areas 3.10 and 3.13 require a minimum TRL/KRL of 4.

*NOTE: Full definitions of TRLs can be found here. More information regarding KRLs can be found here.

4. Represent New Submission to MTEC: The focus of this effort is on proposed solutions that have not been submitted to MTEC under previous RPPs within the past 2 years, including the 22-02-MPAI and 23-06-USAMRDC-MultiTopic. The Government is already aware of concepts submitted in response to previous MTEC solicitations; therefore, such projects are not allowed to be resubmitted here. **This RPP is intended only for submission of new projects to MTEC or substantially revised or modified proposals in accordance with previous Government feedback, not identical resubmissions.**

5. Align to a Specified Focus Area of Interest: Enhanced White Papers shall align to a single Focus Area of Interest specified in Section 3.3 below. Failure to align to a single Focus Area of Interest may result in an "Unacceptable" rating and render the proposal ineligible for award.

****NOTE:** Failure to meet any or all of these minimum requirements may result in an overall "Unacceptable" rating of the Enhanced White Paper with minimum or no additional feedback provided.

3.3. Focus Areas of Interest

To meet the intent of this RPP, each Enhanced White Paper ***SHALL*** specifically address ***ONLY ONE*** Focus Area of Interest described below. Offerors are not limited to a single Enhanced White Paper submission. Projects that fail to align with only one of these Focus Areas of Interest may not be considered for funding.

FOCUS AREA 1 – COMBAT CASUALTY CARE: Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, there is a need for medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. This area prioritizes technologies that are easily transportable (i.e., small, lightweight, and durable in extreme environments and handling), easy to use and require low maintenance. **The following are Focus Areas of Interest (not listed in order of importance):**

- **FA 1.1 - Blood Product Development:** Next generation resuscitation technologies and strategies to extend the shelf-life and/or minimize the cold chain for whole blood and other

blood products. This may include optimization of storage techniques or development of novel technologies that function similarly to blood products in terms of volume expansion, hemostasis, and oxygen carrying capabilities. Potential technologies may include infusible hemostatics (i.e., nanoparticle solutions), oxygen carriers, and combination blood products. Technologies should effectively manage hemorrhage with attributes that include ease of delivery/use, extended shelf-life, and storage in extreme conditions. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to clearance or approval by the U.S. Food and Drug Administration (FDA) in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.2 - Anti-shock Pharmacology:** Evaluation of drugs to mitigate the pathophysiology associated with hemorrhagic shock. Therapeutics should address metabolic acidosis, mitochondrial dysfunction, and/or trauma-induced coagulopathy. Priority will be given to evaluation of existing pharmaceutical technologies that can be repurposed for this indication. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to FDA approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.3 - Battlefield Pain Control:** This focus area of interest is seeking novel solutions (i.e., analgesics and anesthetics) to manage acute battlefield pain that are devoid of performance-limiting side effects. Therapeutics should address the management of pain following traumatic injury (i.e., hemorrhage) and impacts to cardiovascular and respiratory responses. Solutions may include systemic therapeutics, as well as next generation regional analgesia techniques. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.4 - Organ Support Devices and Therapeutics:** Novel technologies and optimization of current technologies are required to provide renal support in the austere setting and treat ischemia reperfusion injury in severely injured casualties. Solutions may include pharmaceuticals or medical devices. All solutions should prioritize ease of delivery and the need for reduced size, weight and power (SWAP). ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.5 - Surgical Support Technologies:** This focus area of interest is seeking novel solutions to extend surgical capability and enable surgical procedures to be safely performed at Roles

of Care 2-3.[2] Current surgical capabilities are relatively cumbersome and more mobile surgical capabilities typically have significantly reduced patient capacity. Novel solutions should increase surgical capacity and decrease SWAP requirements, contributing to improved mobility. This focus area includes both surgical technologies as well as technologies that enable forward surgical capability such as advanced imaging, surgical sterilization, and intelligent anesthesia capabilities. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.6 - Complex Wound Management:** Advanced wound management therapies and solutions for operationally relevant trauma injuries such as complex soft tissue, open fracture, penetrating torso, and blast injuries. Additionally, development of solutions for delays in care of penetrating abdominal injuries and prevention/management of deep space infections are of particular interest. Proposed solutions should be optimized for far forward use with low SWAP requirements. Priority will be given to technologies that can be applied early in the treatment course following injury or initial debridement in order to impact the trajectory of wound recovery. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs.

- **FA 1.7 - Burn Wound Recovery:** This focus area of interest is seeking safe, effective, field deployable, topical and/or systemic treatment capabilities (i.e., best practices/Clinical Practice Guidelines) to promote rapid recovery of skin functions following deep partial thickness and/or full thickness burn injury, agnostic of mechanism. This may include novel and/or repurposed therapeutics capable of initiating/accelerating burn wound healing and closure (including temporary or permanent coverage). Prioritized candidate solutions will reduce follow-on medical care required for full functional recovery, improve burn-injured Warfighter function far forward in austere or prolonged care scenarios, avoid post-burn complications, as well as improve long-term clinical and functional outcomes. This topic prioritizes capability development other than antimicrobial treatments. Studies focused primarily on developing a delivery platform are of significantly less interest compared to studies of the efficacy of the novel or repurposed therapeutics themselves. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL 4, where proposed clinical trials and translational studies are of high interest. Enhanced white papers must also describe the pathway to FDA clearance or approval in sufficient detail (where applicable).***

[2] For more information on Roles of Care: ROC_Ref_Card_V12__June_2019.pdf (mtec-sc.org)

- **FA 1.8 - En Route Care:** This focus area of interest seeks advanced methods and/or materiel solutions to enable high volume or prolonged patient movement. Technologies should be supported by preliminary, published data with a focus on mitigating the potential negative effects of patient movement in an operational environment while also optimizing care to multiple patients simultaneously. Additional considerations include functionality and effectiveness under conditions of vibration, acceleration, altitude and extreme environments. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL/KRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs and KRLs.

- **FA 1.9 - Autonomous Care and Evacuation:** This focus area of interest seeks advanced data-driven solutions for the optimization of provider(s) treatment based on dynamic monitoring of available resources and casualty status. Solutions should present an analysis of critical factors (e.g., casualty status, casualty location, number of providers, medical supplies, environmental constraints, etc.) and an artificial intelligence/machine learning (AI/ML) algorithm which optimizes casualty priority and provider alignment/assignment to increase clinical capacity at the point of injury. Solutions should focus on the clinical aspects of optimizing triage, patient management, and medical regulating, rather than logistics or re-supply. It is encouraged that the algorithmic solution be compatible/capable of being deployed with existing field medic platforms (such as BATDOK, MEDCOP, etc.). ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL/KRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs and KRLs.

- **FA 1.10 - Semi-autonomous Procedural Support:** This focus area of interest seeks technologies that enable semi-autonomous assistance for resuscitative procedures using AI and robotic technologies. These technologies should optimize the technical completion of the necessary task through speed, efficiency, and accuracy in order to improve the safe completion of the procedure while mitigating training decay and differences in provider expertise. Example technologies include facilitating venous and arterial access, as well as regional analgesia. ***Offerors submitting proposals to this focus area of interest must provide preliminary/published data in the Enhanced White Paper that supports a minimum TRL/KRL 4 and describe the pathway to FDA clearance or approval in sufficient detail (where applicable).*** See section 3.2 of this RPP for more information related to TRLs and KRLs.

- **FA 1.11 – Military-Civilian Partnerships for Trauma:** This focus area aims to develop and implement a pilot program that expands an already existing military-civilian partnership focused on training and sustainment of military personnel for the care and treatment of traumatic injuries and the conduct of military-relevant research and development. The Enhanced White Paper shall briefly outline the proposed methodology to demonstrate a course of action that: i) evaluates return on investment for military-civilian trauma

partnership models, including clinical productivity, financial metrics, skill acquisition metrics and academic/research productivity; ii) evaluates, optimizes, and validates training and sustainment methods for military personnel within these partnerships; and iii) optimizes partnership models for successful conduct of military relevant research and development in the care of traumatic injuries. The Enhanced White Paper shall briefly outline the proposed methodology to the extent possible that demonstrates the Offeror's capability and its understanding of the resources (to include subject matter experts, subcontractors, and potential prototypes under development) required to address this technical requirement. This focus area of interest will prioritize already existing military-civilian partnerships with the aim to optimize them for trauma training and military relevant trauma research, rather than establishing new partnership sites. It is encouraged that proposed projects include the following:

- Access to study populations and existing data already collected from human subjects that support the goals of this program and the ability to maintain and interpret these data;
- Ongoing relationships with both non-Government and DoD organizations that comprise the military-civilian partnership;
- Experience with care and treatment of traumatic injuries in civilian populations that translate to military-relevant use cases;
- Access to prototypes in development for the care and treatment of traumatic injuries;
- Access to human patients with traumatic injuries [to compare with military patients to build the capability of predictive models and strategies for clinical interventions]; and,
- The focus to be metric-driven with requirements for prototype development toward clinical interventions, endpoints, policy and processes for the care and treatment of traumatic injuries.

It is expected that outcomes will be transitioned to inform prototype development for military-relevant use cases, clinical practice guidelines, training, and clinical trial endpoints.

- **FA 1.12 – Studies in Ukraine:** The current conflict in Ukraine provides an unprecedented opportunity to understand medical care and challenges associated with modern large scale combat operations. Section 736 of the Fiscal Year 2023 National Defense Authorization Act has directed the U.S. DoD to seek partnerships with Ukraine in the area of trauma education and research. This funding opportunity prioritizes both capability development and study of medical care challenges within the current conflict. ***NOTE: Enhanced White Papers submitted to this focus area of interest must provide a clear benefit to the Ukraine system of care, as well as providing lessons learned for the U.S. military medical system in anticipation of potential future large-scale conflicts. At the time of proposal submission, Offerors must provide documentation of: 1) Ability to conduct work within Ukraine without U.S. personnel entering the country; 2) Evidence of a capable Ukrainian partner and any necessary support from the Ukraine Ministry of Health or Ministry of Defense; <u>and</u> 3) Where appropriate, a clear plan for necessary regulatory, ethics, and human protections approvals within the U.S. and Ukraine.***

The following two focus areas of interest **are** listed in order of priority:

- **FA 1.12.1 - Clinical Trial Capabilities:** This focus area aims to develop and implement a pilot program focused on 1) developing observational and/or interventional human subject testing capabilities, and 2) using these capabilities to conduct clinical studies related to care of the war wounded in Ukraine. Example areas in need of these clinical capabilities and subsequent evaluation include, but are not limited to: wound infection/management, tourniquet use, hemorrhage and resuscitation, evacuation, traumatic brain injury, rehabilitation and traumatic stress. Of particular interest is the impact of time delays between wounding and initial care as well as throughout the care continuum. Trauma registry development and data analysis is an additional priority.

- **FA 1.12.2 – Evaluation of Casualty Care Technologies in Ukraine:** This focus area of interest aims to evaluate, optimize, and/or validate casualty care technologies for use in the forward operational environment. Examples of proposed studies could focus on the evaluation of utility, ease of use, compatibility with the forward operating environment, and clinical outcomes. The project deliverable could also include recommendations for technology improvements to optimize use in the forward operating environment. Priority will be given to proposed casualty care technologies that are (not listed in order of importance):
  - currently in development by the U.S. DoD;
  - have obtained regulatory clearance/approval from a European body and interested in pursuing approval via the U.S. FDA; or
  - have obtained regulatory clearance/approval by the U.S. FDA but need funding for validation studies in a forward operational environment.

FOCUS AREA 2 – MILITARY INFECTIOUS DISEASES: This technology area focuses on vaccines, drugs, vector detection assays, and novel therapeutics to treat multidrug-resistant organisms in combat wound infections, as well as vector control measures for insect vectors that transmit naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. This area specifically focuses on solutions for prolonged care scenarios, where wound infection poses a significant threat to operational readiness and effectiveness, as well as solutions enhancing medical readiness in response to infectious diseases encountered by Service members during deployment that can significantly impact performance. **The following are focus areas of interest (not listed in order of importance):**

- **FA 2.1 - Prophylactic to Prevent Infection in Battlefield Wounds from Complex Traumatic Penetrating Injuries in a Far-Forward, Austere Environment:** This focus area of interest seeks the development of materiel solutions that have the following **required** solution characteristics:
  - Must be able to conform to 3-dimensional wound shape (i.e., not a bandage)
  - Must be self-absorbing or removable through wound irrigation

- Must be effective against at least one, but preferably multiple, high priority pathogens: *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*
- NOTE: Offerors must include preclinical efficacy data in the enhanced white paper at the time of submission.

In addition, it is **strongly preferred** that proposed solutions provide the following desired solution characteristics:

- Integration of novel antibiotic drug classes against Gram-negative pathogens
- Single solution with ability to provide antibiotics, pain analgesics, and/or hemostasis compounds

At the time of proposal submission, it is **strongly preferred** that Offerors also include the following in their enhanced white papers:

- Toxicity data (if required by FDA)
- Regulatory strategy with documented FDA engagement (including minutes from pre-submission meetings)

- **FA 2.2 - Pathogen Agnostic Countermeasures for the Treatment of Sepsis Caused by Wound Infection:** Development of drug / biological treatments for sepsis, including host-based therapeutics.
  - Offerors must include preclinical efficacy data in the enhanced white paper at the time of submission.
  - Toxicity data (if required by FDA) are preferred

- **FA 2.3 - Antivirals for the Prevention and/or Treatment of Endemic and Emerging Infectious Diseases (Non-biothreat Pathogens):** Development of broadly acting antivirals (small molecules, innovative antibody approaches, repurposed antivirals) that can be administered via oral (PO), intramuscular (IM), transdermal (TD) or subcutaneous (SC) routes (Intravenous (IV) not preferred) that are effective against pathogens relevant to the military:
  - Two or more pathogens from the Bunyavirales order (e.g., Lassa virus, Crimean Congo Hemorrhagic Fever virus, Severe Fever with Thrombocytopenia Syndrome virus)
  - The Flaviviridae family with Dengue virus as the primary target (against all four serotypes) and all other flaviviruses as secondary targets

  NOTES:
  - Offerors must include preclinical efficacy data in the enhanced white paper at the time of submission.
  - Inclusion of toxicity data (if required by FDA) are preferred.
  - Regulatory strategy with documented FDA engagement (including minutes from pre-submission meetings) is strongly preferred

- **FA 2.4 - Prevention of Endemic Diarrheal Diseases:** Development of immunoprophylactics for endemic viral diarrheal diseases, with a focus on norovirus.
  NOTES:
  - Offerors must include preclinical efficacy data in the enhanced white paper at the time of submission.
  - Inclusion of toxicity data (if required by FDA) are preferred.

- **FA 2.5 - Knowledge Product Solutions for the Prevention of Infection in Traumatic Penetrating Wounds:** Solutions are expected to optimize clinical practice guidelines for at least one of the following **(not listed in order of importance):**
  - **FA 2.5.1** - Decipher the intricate relationship between combat polytrauma, infections and sepsis for data-driven clinical practice guideline revisions and field medicine.
  - **FA 2.5.2** – Modernize the effectiveness of acute traumatic wound management. Proposed projects shall 1) assess the effectiveness of the Acute Traumatic Wound Management guidelines[3] and 2) optimize these guidelines to enhance the standard of care for traumatic wound infectious found in operational environments. It is encouraged that proposed projects have access to study populations and data already collected from human subjects that support the goals of this program and the ability to interpret these data. The project shall deliver translatable processes, knowledge and technology (i.e., training, clinical practice guidelines for assessment and interventions, and clinical trial endpoints) to optimize and inform care for traumatic wound infections found in operational environments.
  - **FA 2.5.3** - Leverage polytrauma of infection preclinical models to evaluate emerging solutions and therapeutics that target infections of traumatic penetrating wounds, identifying refinements needed for solution maturation.

FOCUS AREA 3 – MILITARY OPERATIONAL MEDICINE: This technology area aims to maximize health, readiness, and performance by countering stressors and preventing physical and psychological injuries during training and operations. **The following are focus areas of interest (not listed in order of importance):**

- **FA 3.1 - Individual Occupational and Environmental Exposure Monitoring:** The development and refinement of a health assurance platform integration with environmental and physiological sensor technologies for individual occupational and environmental exposure monitoring. Required capabilities include the integration and testing of specialized volatile organic compound and fine particulate matter sensing capabilities; algorithms for environmental hazard monitoring and physiological effects; development of a suite of modules enabling remote monitoring of bio-fluids for examination of biomarkers and exposure levels; and operational validation of the above capabilities in at least one or more military-relevant environments.

[3] https://jts.health.mil/assets/docs/cpgs/Wound_Management_PFC_24_Jul_2017_ID62.pdf

- **FA 3.2 - Advanced Research Using Multi-enclave AI Analytics of Biomedical Readiness for Formation-centric Military Performance:** Required capabilities include the ability to perform AI analytics on biomedical readiness data, to include the synthesis of medical readiness and training readiness collected at point of need and transferred as required, across multiple network enclaves with differential security / firewall permissions. Demonstration of analytic and/or data movement capability required in military-relevant environments with military formation-centric focus, either garrison / training or deployed or both.

- **FA 3.3 - Understanding Tinnitus:** Mitigating tinnitus will sustain Soldier lethality in multi-domain operations. Tinnitus can have severe effects on battlefield situational awareness and diminish the effectiveness on Soldier readiness. Depending on severity, tinnitus can impact effective communication within military maneuver units and/or airborne air support craft. Tinnitus and hearing loss are the top two disabilities for all Veterans awarded compensation for service-connected disabilities. The underlying cause of tinnitus is not known, and there is no objective test for tinnitus. The overall objective of this focus area of interest is to advance effective strategies to prevent, test, manage and treat for this condition. Enhanced white papers will be expected to propose studies that assess the physiological effects of service-related neurosensory traumatic injury on the onset and progression of tinnitus. Prototype solutions may address the impact of tinnitus by optimizing the restoration and rehabilitation processes of hearing following service-related neurosensory traumatic injury. Proposals may also aim to provide recommendations and/or propose mitigation strategies to improve or refine the development of or existing prototypes used in relation to tinnitus.

- **FA 3.4 - Leverage Medical Health Data for Neurosensory Injury Prevention and Treatment Strategies:** Leveraging medical health data has become a DoD-wide focus. Neurosensory injuries such as optical trauma, hearing loss and vestibular dysfunction, are prevalent among military personnel due to the nature of their duties. By leveraging medical health information, comprehensive information about the occurrence, patterns, and outcomes of these injuries could be gathered. This data enables researchers and healthcare providers to identify risk factors, develop preventive measures, and design targeted treatment strategies for military exposure induced neurosensory injuries. It also facilitates the monitoring and evaluation of interventions, leading to evidence-based practices and can improve both the short-term and long-term outcomes for the neurosensory injury in the military context. This focus area of interest seeks data-driven insights and recommendations to enhance prevention strategies and inform treatment protocols, and may potentially lead to the follow-on work related to improved prevention, management and treatments of neurosensory injuries. Proposed work may include the following activities:
    - Collect and analyze medical health data from service members to identify patterns, associations, and governing forces related to neurosensory injuries to inform prevention and treatment strategies.
    - Incorporate military hazardous exposure data, such as noise exposure levels, duration, and specific environments, in conjunction with medical health data to

discover hidden correlations and risk factors that could inform prevention and treatment strategies.
- Utilize advanced data analytics and machine learning techniques to identify and develop predictive indicators, potential intervention strategies, and personalized risk assessments for neurosensory injuries.

- **FA 3.5 – Hearing Protection Communication:** Hearing protection devices (HPDs) are essential safety equipment for military personnel, who are routinely exposed to high-intensity sounds that can permanently damage hearing. However, HPDs also impair situational awareness and communication. Warfighters are acutely aware of such side-effects and their impact on performance in key operational tasks, contributing to disuse in the same operational settings where injurious high-intensity sounds are common. The subsequent loss of hearing results in an immediate degradation of operational capability, impeded communications, and significant disability payments after service completion. Advancements in HPD technologies are necessary to mitigate the negative perceptual side effects of HPDs.

  This Focus Area of Interest is concerned with the evaluation and enhancement of HPDs in simulated operational environments (e.g., 3-dimemntional multi-source sound fields). Proposed solutions may generate knowledge products to inform and/or refine HPD prototypes currently in use or under development. Offerors are encouraged to align proposals to the short-, mid-, or long-term goals of this effort:
  - **FA 3.5.1 –** Short-Term Goal: Evaluate the performance of HPD technology under military operationally relevant conditions to determine deviations from laboratory measurements.
  - **FA 3.5.2 –** Mid-Term Goal: Develop and incorporate advanced acoustic technologies to mitigate adverse perceptual side-effects of HPDs.
  - **FA 3.5.3 –** Long-Term Goal: Evaluate the effects of HPD technology on enhanced human performance during key operational and military-relevant tasks and optimize HPD technology for the military environment as needed.

- **FA 3.6 - Brain Computer Interface (BCI) Translations:** Advancements in BCI for vision restoration have the potential to benefit military service members who may have acquired vision loss due to military traumatic injuries, improving their quality of life and the ability to return to duties. BCI prototypes that are within scope must stimulate part of the visual pathway, such as the retina, optic nerve, and visual cortices, to generate visual perceptions. This effort is looking to fund a human study or clinical trial focused on using BCIs, specifically visual neural prostheses, to offer a more direct approach to restore vision. Offerors with an approved Investigational Device Exemption by the U.S. FDA are strongly encouraged for this focus area.

- **FA 3.7 - Temporary Cornea Repair (TCR):** Ocular injuries are a major cause of battlefield casualty and permanent disability and represent a threat to operational readiness and a socioeconomic burden. Closure of these injuries requires surgical intervention by an

ophthalmologic surgeon and most often must occur within 24 hours to preserve any amount of residual vision, with the time to primary surgical repair strongly correlated with final visual acuity. Delays in initiation of pre-operative treatment in animal models of eye injury have been shown to have a negative impact on physiological values associated with injury severity, and case studies indicate that delays in pharmacological treatment for endophthalmitis correlate with worse outcomes, suggesting that acute care in the emergency setting has the potential to improve outcomes. Currently DoD is lacking solutions to address this military requirement for ocular injuries in the battlefield. Proposed solutions must address at least one of the following requirements:

- A near-term solution that could repurpose an FDA-approved surgical aid-indicated solution already shown to improve wound healing efficacy in clinical trials. This should be an expanded indication without the need for a full New Drug Application to the FDA and the full scope of clinical trials, suggesting the potential for a near-term solution meeting all research requirements.
- To develop a medium-term solution that would likely to require funding of advancement in cGMP-capable manufacturing of the prototype and FDA device approval. Such a solution is likely a medium-term solution requiring an estimated minimum of 3 years of effort with consistent funding and real property investment in manufacturing capability.
- To develop a far-term solution with FDA approval eye stabilization device for Role of Care 1 as a result of the improved safety profile in animal studies and apparent therapeutic effects. It would be expected that no aspect of this potential solution has reached any stage of clinical testing in humans, and this approach also requires the development of a new FDA-approved eye shield device.

- **FA 3.8 - Psychological Health, including Psychological Disorders Treatment:** Mature and integrate a scalable, digital health suite of tools that extends options for monitoring and care management of adjustment disorders to behavioral health officers (BHOs), offers self-care for Service members with adjustment disorders in garrison settings who may have limited access to clinical providers, and offers providers and leaders a more upstream evaluation and monitoring of risk-related events/problems and symptoms in members within their units. Of interest is a military-centric digital e-health platform, provider dashboard, and individual app all with military-specific content to mitigate adjustment disorders, and also capabilities for monitoring high frequency events and person-level risk factors for adjustment-related difficulties and offering evidence-based treatment/interventions for one or more of the conditions/issues commonly co-occurring with adjustment disorders (e.g., insomnia, distress) which could be self-administered where appropriate. Requirements for submissions are as follows:
  - The proposed digital platform must have proven (tested) capabilities for secure and asynchronous connectivity, for use in remote and/or austere environments with Active-Duty Service Members (ADSM)
  - Offeror must provide established supporting data on their platform's feasibility and acceptability in ADSM and military provider populations

- Must use psychometrically-sound measures
- Must align to be compatible with existing DoD Behavioral Health tools used by BHOs (e.g., the BH Pulse).
- Offeror must have a verifiable plan for access to an ADSM population to conduct the research to further test this platform and content for effectiveness of the interventions and BH monitoring capabilities.
- Teaming is strongly encouraged, especially with DoD research laboratories who have expertise in these content areas. Datasets regarding existing DoD Behavioral Health tools in use (e.g., BH Pulse) may be available for sharing/leveraging upon award.
- Must provide a letter of support from a U.S. military commanding officer stating Offeror's access to and participation by ADSM population. Proposals without appropriate letters of support may be withdrawn.

- **FA 3.9 - Objective Behavioral Health Assessment and Monitoring:** Non-invasive assessment and monitoring of behavioral health-related conditions and symptoms (e.g., depression, post-traumatic stress disorder (PTSD), acute stress reactions, acute stress disorder, pain, somatic symptoms) using analysis of paralinguistic features from audio recordings acquired immediately after a potentially traumatic event (e.g., car accident, assault), and the following weeks of recovery. The desired use case for this prototype would be identifying if behavioral health symptoms are improving or declining, and/or using predicting changes in symptoms from one timepoint to the next.
  - Proposals utilizing AI/ML approaches should be substantiated by demonstrating expertise in this field.
  - Offeror must provide a description of the supporting preliminary data demonstrating a TRL 3 which will be used to refine analyses of paralinguistic markers.
  - Use of publicly available paralinguistic analysis packages are acceptable and encouraged

- **FA 3.10 - Effective, Scalable Treatments for Full Remission:** Evaluate and refine scalable treatments or treatment regimens that maximize full remission of PTSD or Adjustment Disorders symptoms in ADSM populations, to maintain medical readiness.
  - Must provide preliminary treatment/intervention data from clinical trials that can inform refinement strategies and hypotheses.
  - Minimum of KRL 4 is required for submission of an Enhanced White Paper to this focus area of interest, such as already having completed pilot intervention trial.
  - Proposals for new (initial pilot) treatment clinical trials will not be considered.
  - Therapies for co-occurring PTSD and Alcohol Use Disorder will not be considered for this RPP, as this topic area is resourced by a separate Program.
  - Given the shortage of behavioral health clinicians in the U.S., the preferred treatments are those which are more scalable, such as portable neuromodulation, stellate ganglion block, or other non-psychotherapy treatments. Scalability includes considerations for the required personnel resources (i.e., avoid treatments that solely rely on psychologists and other highly trained and experienced behavioral health

personnel to administer in a 1:1 regimen), individuals' logistical barriers to care, highly specialized or lengthy provider training, unit cost per person, etc.
- Must provide a letter of support from a U.S. military commanding officer stating Offeror's access to and participation by ADSM population. Proposals without appropriate letters of support may be withdrawn.

- **FA 3.11 - Postventions for Suicide:** Development of theory-based military-specific postventions for suicide, particularly after discharge from in-patient treatment for suicide ideations or attempt (e.g., reintegrating Service Members back into their unit/installation), after a suicide exposure, or during the transition phase from active duty to Veteran status. Postvention solutions may include but are not limited to crisis response plan components, military peer/buddy resources, lethal means safety interventions, or other evidence-based interventions for postvention support. Proposed solutions should be intended for use by non-clinical personnel (e.g., military leaders, peers, family, unit prevention staff, or chaplains) and should be developed with the intention to transition into military installations.

  Populations of interest for this Focus Areas include:
  - Active Duty Service Members
  - National Guard or Reserves
  - Military Service Academy Service Members, and/or Reserve Officers' Training Corps

  Populations NOT of interest include:
  - Veterans
  - Personnel in retired military status

  Solutions NOT of interest include:
  - Passive sensing, or "wearables"
  - Artificial intelligence technology-based algorithms for monitoring or predicting harmful behaviors
  - Technology solutions that are intended as clinical decision support tools
  - Mobile applications or platforms that have not already been integrated in the DoD
  - Any technological product that requires FDA approval and is not currently FDA approved

- **FA 3.12 - Cross-Cutting Prevention:** This Focus Area of interest seeks theory-based research to support program, training, or intervention development, efficacy/effectiveness testing, and implementation of military primary prevention approaches that have cross-cutting impacts on multiple harmful behaviors, including suicide, sexual assault/violence and harassment, ostracism, domestic abuse, and alcohol and substance misuse. Solutions for this focus area of interest are intended to be comprehensive prevention approaches that address multiple ecological levels (e.g., individual, unit, installation, leadership), to promote healthy behaviors and reduce risk factors for harmful behaviors. Solutions should be designed with the intention to transition into military installations.

Populations of interest for these Focus Areas include:

- Active Duty Service Members
- National Guard or Reserves
- Military Service Academy Service Members, and/or Reserve Officers' Training Corps

Populations NOT of interest include:

- Veterans
- Personnel in retired military status

Solutions NOT of interest include:

- Passive sensing, or "wearables"
- Artificial intelligence technology-based algorithms for monitoring or predicting harmful behaviors
- Technology solutions that are intended as clinical decision support tools
- Mobile applications or platforms that have not already been integrated in the DoD
- Any technological product that requires FDA approval and is not currently FDA approved

- **FA 3.13 - Warfighter Fitness to include Musculoskeletal Injury Prevention and Treatment** Proposed solutions **must be at a minimum TRL 4 (clinical studies preferred)** and should relate to at least one of the following areas (not listed in order of importance):
  - Validated musculoskeletal injury risk screening and assessment tools to identify individual and unit-level musculoskeletal injury risk and performance decrements.
  - Advancement of imaging devices or objective assessment tools that can accurately distinguish bone, muscle, tendon and/or ligament injury and recovery.
  - Biologic or drug therapy that can speed recovery of minor tendon/ligament injuries in an operational environment for rapid return to duty. Animal studies are not permitted.
  - Solutions to design AND develop AND implement training programs for Warfighter health and fitness.

- **FA 3.14 - Performance Decrement and Injury Risk in Ground Soldiers due to Head Supported Mass (HSM):** Operationally-relevant helmet and helmet-borne system (or HSM) guidance to minimize performance decrement is needed for dismounted Soldier populations. Using biomechanical/physiologic, operational performance, and user feedback data obtained human subject volunteers, HSM guidance will be generated to provide thresholds on HSM properties (mass and longitudinal CM offset) to material developers and health hazard assessors specifically for dismounted Soldier populations. Offerors are encouraged to address the following in their proposals:
  - Leverage computational models to assess the biomechanical response of the human spine during dismounted operations.

- Use physiologic, biomechanical, and kinematic data collected during DoD human subject field- and lab-based testing as inputs into newly developed or existing musculoskeletal models to assess spinal response to HSM.
- Perform static and dynamic optimizations of cervical spine movements associated with dismounted maneuvers and techniques with vary HSM conditions.
- Conduct analyses to estimate metrics such as ligament strain, intervertebral stresses, joint angles, joint forces and moments, and muscle forces under different HSM conditions.

The metrics will assist in the extrapolation of both operational performance decrement and potentially injurious effects resulting from HSM exposures. The Offeror's ability to associate these model-predicted outputs with the reported spinal pain symptomology and other applicable medical outcomes or health effects that have been associated with HSM exposures such as neck pain/discomfort, neck muscle activation, and neck fatigue will support the development of guidance and thresholds to minimize HSM-related operational and biomechanical performance decrement.

- **FA 3.15 - Biomechanical Tolerance of the Human Head to High-Rate Localized Blunt Impacts:** Injury criteria for high-rate blunt impacts to the head, such as those resulting from ballistic-induced behind helmet blunt trauma, are required to develop injury -based performance criteria for DoD personal protective equipment (PPE). The purpose is to have medically based criteria for future development and evaluation of next generation PPE. There is also a need to develop medically-based performance requirements for helmets in order to protect against the whole spectrum of head/brain injuries occurring in military operational environments. Offerors are encouraged to address the following in their proposals:
  - Leverage existing published literature, and previous DoD-funded projects investigating head injuries caused by blunt impacts at loading rates ranging from sports-related impacts and motor vehicle accidents to behind-armor blunt impacts resulting from defeated ballistic projectiles.
  - Leverage existing and emerging clinical data and emerging field data on head injuries being collected by the DoD, law enforcement community, industry, and academia.
  - Develop and conduct, in cooperation with DoD laboratories, innovative medical research to characterize physiological response (e.g., head injury, traumatic brain injury), and head impact parameters under military-relevant exposures, using mechanical, cadaveric, or animal surrogates.
  - Collaborate with DoD laboratories, industry, and academia to leverage existing computational models of the head, brain, and torso to support, and potentially expand, the experimental studies mentioned above.
  - Correlate physiological response to impact parameters to develop and deliver injury risk thresholds or probability risk curves for head injuries related to high rate localized blunt impacts.
  - Collaborate with DoD laboratories with complementary capabilities to leverage DoD research expertise and to ensure operational relevance of the proposed research.

FOCUS AREA 4 – U.S. AIR FORCE SCHOOL OF AEROSPACE MEDICINE: The Air Force Aerospace and Operational Medicine Enterprise (AOME) seeks to maximize Airman performance and readiness, as well as the development of mitigation measures for physical and psychological stressors, illness and injuries during Airman training and operations by executing studies and analyses. The Studies and Analysis Portfolio general focus areas can be broadly categorized into the following areas of interest: Aerospace Medicine and Physiology, Public Health and Preventative Medicine, Occupational Medicine and Bioenvironmental Engineering, and En Route Care and Expeditionary Medicine. The following focus areas of interest are based on urgent and near-term needs and issues identified within the Air Force (AF) population. **Proposals must be appropriate for one-year (12 month), short term investigations to address focus areas of interest listed below (not listed in order of importance):**

- **FA 4.1 - Musculoskeletal Injury Prevention and Treatment for Aircrew and Maintainers**: Neck and back pain is a known occupational hazard for the high-performance aircraft community. The government seeks solutions, including tools to prevent, reduce, screen and diagnose musculoskeletal condition as well as alternative/integrative medicine approaches, for prevention or treatment of musculoskeletal injuries. Proposed solutions shall focus on providing reliable measurements to determine platform-specific neck/back dysfunction and improvements due to embedded care.

- **FA 4.2 - Aerospace Physiology:** Solutions relating to the physiologic assessment in high altitude Fighters/Trainers. Solutions should relate to at least one of the following areas (not listed in order of importance):
    - Assessments of the physiologic response to exposures and stressors from the fighter/trainer environment; can cover any of the following: including effects of fluctuating pressure, high O_2, air quality, breathing resistance, thermal burden, dehydration, rest/sleep (physical fatigue), cognitive fatigue, Aircrew Flight Equipment (AFE) integration (how AFE impacts in-flight physiology, and how AFE components interact with each other to impact physiology and aircrew performance), and combined stressors on performance and decision making in ground-based testing and operational environments, including the analysis of potential countermeasures to optimize pilot performance and eliminate sources of risk.
    - Solutions to sustain Aircrew performance in extreme environments.
    - Conduct a comprehensive technology assessment of the current military health system simulators that can monitor and track physiologic responses from training student pilots.
    - There is a strong demand for wearables that are cross compatible across multiple systems to collect physiologic data, that are reliable and validated in the operational environment. Offerors are to conduct a comprehensive technology assessment of commercial off the shelf products, including their suitability for use in the operational environment and their validated measurement capabilities, to help aid aircrew and decision makers on what can be flown in the aircraft and what can be accurately collected from those sensors.

- **FA 4.3 - Carcinogens (*source NDAA 2021 Sec 750*):** Proposed projects are expected to relate to at least one of the following areas (not listed in order of importance):
  - Development and evaluation of prototypes that can identify carcinogenic toxins or hazardous materials associated with military flight operations from shipboard or land bases or facilities.
  - Development and evaluation of prototypes that can identify exposures to ionizing radiation and nonionizing radiation from which airmen could have received increased radiation amounts.
  - Establishment of guidelines for carcinogen exposure as it relates to demographics for each airman to include duty stations, duties and aircraft flow.
  - Establishment of guidelines that outline the duties and potential exposures of airmen that are associated with higher incidence of cancer.
  - Development and evaluation of screening tools and/or methods that relate to carcinogen exposure to airmen.

- **FA 4.4 - Precision Medicine and Medical Standards**: Development of solutions relating to at least one of the following areas (not listed in order of importance):
  - Surveillance of conditions, indications, clinical practice guideline adherence, and outcomes to support cost benefit analyses for AF population.
  - Genomics for mishap investigations (gene expression, subtracting human and molecular autopsy).
  - Studies providing data to support evidence-based aerospace medicine standards.
  - Psychological Performance and Mental Health (solutions should relate to at least one of the following areas; not listed in order of importance):
    - Mental health and psychological disorders amongst airmen and potential influence on readiness and retention.
    - Neurocognitive diversity; cognitive testing and correlates with mental health and other outcomes.
    - Assessment of the feasibility of integrating the use of personality data and wearable technology to facilitate adjustment and success during career specific training. Personality assessments and wearables as tools to facilitate positive change, well-being, and performance by increasing self-awareness.

- **FA 4.5 - En Route Care & Expeditionary Medicine**: Needs in this area include enabling medical capabilities to support en route care to/from remote, austere settings, and in extreme Environments. This area can also include training methodologies to improve operational readiness for individuals and teams within the en route care environment. Proposed solutions should be cognizant of AF capabilities and needs as noted in the Air Force Doctrine Publication (AFDP) 4-02.[4]

[4] https://www.doctrine.af.mil/Doctrine-Publications/AFDP-4-02-Health-Services/

3.4. Additional Points of Consideration

- Project Maturity: This solicitation is not meant to support development of a new prototype and shall meet the minimum TRL or KRL requirement of 3 or otherwise stated in Section 3.3 (see Section 3.2 for more information regarding TRLs and KRLs). Offerors shall adequately describe how their proposed technology meets the definition of a prototype and should clearly address how the prototype meets the indicated TRL or KRL at the time of submission. See **Addendum 1** for a reference checklist to assist in assessing the TRL of the proposed project.

- Industry Partners: Proposed projects are encouraged to include relevant industry partners, especially considering that the eventual goal is to transition products to industry for U.S. FDA approval and/or commercialization.

- Cost Share**:** It is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.

3.5. Examples of Proposed Tasks

The PoP should be focused on tasks relevant to advance the prototype to the next TRL or KRL. Project scope should be proposed based on the prototype's maturity at the time of submission. **Examples** of the work that could be included in the PoP are **(but not limited to)**:

- Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design
- Exploratory study of candidate devices/systems/drugs
- Candidate devices/drugs/vaccines are evaluated in laboratory or animal model(s) to identify and assess potential safety problems, adverse events, and side effects
- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Preparation of regulatory packages (e.g., Investigational New Drug application, Investigational Device Exemption application), including regulatory consultant costs.
- Prototype refinement/maturation progressing towards clinical product
- Clinical feasibility studies (as needed) to support regulatory approval/clearance
- Clinical pivotal studies (as needed) to support regulatory approval/clearance
- Stability and shelf-life studies
- Prototype delivery for military-relevant testing
    - Testing of prototypes
    - System prototype demonstration in a relevant or operational environment
- Establishment of Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release

- Draft product support documentation (e.g., training guides, product inserts, etc.)
- Development of a business and/or commercialization plan for market release
- Integration of medical informatics system components and system is evaluated in a simulated environment/ Develop interfaces to supporting systems
- Advanced technical testing in a laboratory environment and ultimately in a relevant or simulated operational environment of an informatics system including actual interfaces to realistic supporting elements

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 initial PoP. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. **Examples** of potential follow-on work are **(but not limited to)**:

- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Clinical Studies
- Establish robust quality system
- Improve efficiency and reproducibility of manufacturing process for scale up
- Work towards FDA clearance/ approval
- Military environmental and operational assessments
- Ruggedization for operation in military environments
- Advanced technical testing in relevant or simulated operational environments

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, Human Anatomical Substances, or Human Cadavers

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's (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 review. Allow a minimum of 2 to 3 months for OHRO regulatory review and approval processes.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO 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.

Proposals 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 IRB, but at a minimum, annually), and approval by the USAMRDC OHARO. Offerors shall include IRB and OHARO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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

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

3.8. Inclusion of Women and Minorities in Study

Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Under any resultant awards, Offerors may be required to describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Such strategy should provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from the Documents Library on the MTEC Public Site (mtec-sc.org) and the Members Only Site.

3.9. Guidance for research studies targeting DoD personnel for survey research

Protocols that target DoD personnel for research in which the primary data collection tool is a survey require additional administrative review per Department of Defense Instruction (DODI) 1100.13. Investigators will need to coordinate with OHARO to identify current submission requirements.

3.10. Guidance for research studies targeting military families and children

In accordance with DODI 1402.5 and Army Directive 2014-23, Child Care National Agency Check and Inquiries (CNACI) background investigations are required for all individuals who have regular contact with military dependents under 18 years of age. All individuals who regularly interact with children under 18 years of age in Army sponsored and sanctioned programs are required to undergo specific initial background checks and periodic re-verifications. Investigators who propose work involving contact with military dependents under 18 years of age should plan for the additional time and funds required for such investigations.

Per Department of Defense Education Activity (DODEA) Administrative Instruction 2071.3, DODEA approval is required for research studies involving DODEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DODEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DODEA to conduct such activities. Procedures and requirements for the review and approval of a research study request can be found at- http://www.dodea.edu/datacenter/research/requests.cfm

Research studies that address Army Family Advocacy Program (FAP) concerns will need to be coordinated with the Family Advocacy Research Subcommittee (FARS) per Army Regulation 608-18.

3.11. Guidance for research studies involving US Army Special Operations Command (USASOC)

Per USASOC policy 24-18, studies involving USASOC as human subjects require additional review by the USASOC Research Advisory Committee and Human Subjects Research Board.

3.12. 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 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 the following 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 may be submitted at any time during the submission period but no later than the due date and time specified on the cover page using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. **The BIDS system will open for submissions no later than October 20, 2023.** Include the MTEC Solicitation Number (**MTEC-24-01-MPAI**) on each Enhanced White Paper submitted. See **Attachment 7 of the PPG** for further information regarding BIDS registration. Instructions regarding BIDS submissions will be forthcoming.

Evaluations and recommendations for award are expected to be conducted on a first-in, first-out basis. Therefore, we highly encourage Offerors to submit as soon as possible during the open submission period. Project awards will be made on a rolling basis.

Evaluations will be conducted individually on a submission-by-submission basis.

Do not submit any classified information in the Enhanced White Paper submission.

The Enhanced White Paper format provided in this MTEC RPP (**Section 8 of this RPP**) is **mandatory** and shall reference this RPP number (**MTEC-24-01-MPAI**). 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.

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 Stage 1 Enhanced White Paper

Offerors submitting Enhanced White Papers in response to this RPP should 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 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 are encouraged to 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) For all Focus Areas: Submitted via BIDS (5MB or lower)

1. **Enhanced White Paper:** one Word or PDF document. The Enhanced White Paper is limited to ten (10) pages including cover page. **(See Section 8 of this RPP for a template)**
2. **Warranties and Representations:** one Word or PDF document **(Attachment 3 of the PPG**)
3. **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**Attachment 4 of the PPG**)
4. **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**Attachment 6 of the PPG**)
5. **Technology/Knowledge Readiness Level Checklist:** one Word or PDF document (**Addendum 1 of this RPP**)
6. **Current and Pending Support**: one Word or PDF document (**Addendum 4 of this RPP**) summarizing other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request.

Supplemental Submission Documents (*as applicable*): Submitted via BIDS (5MB or lower)

- **Extramural Research Involving Human Subjects:** one Word or PDF document (**Addendum 2 of this RPP**). *This is only required if a project involves the participation of human subjects and is conducted solely by a non-federal entity. Alternatively, if available, the Offeror is highly encouraged submit an approved clinical trial protocol instead of Addendum 2*.
- **Documentation of FDA Engagement:** one Word or PDF document (no template provided). *This is highly encouraged for Offerors who are proposing technologies that ultimately require approval or clearance by the U.S. FDA. Offerors are encouraged to demonstrate evidence of prior engagement with the U.S. FDA, for example, meeting minutes, evidence of submissions, FDA feedback documentation, etc.*

Focus Area Specific Submission Documents: In addition to the submission documents described above, several focus areas require additional documents: Submitted via BIDS (5MB or lower)

- **Focus Area 1.12 - Letters of Support:** one Word or PDF document (no template provided) that provides the following: 1) Ability to conduct work within Ukraine without U.S. personnel entering the country; 2) Evidence of a capable Ukrainian partner and any necessary support from the Ukraine Ministry of Health or Ministry of Defense; and 3) Where appropriate, a clear plan for necessary regulatory, ethics, and human protections approvals within the U.S. and Ukraine.

- **Focus Areas 3.8 and 3.10 - Letters of Support:** one Word or PDF document (no template provided) from a U.S. military commanding officer stating access to and participation of an ADSM population in the proposed solution.

- **Focus Area 3.13 - Biographical sketch**: one Word of PDF document (**Addendum 3 of this RPP**) providing a biographical sketch for all key personnel contributing to the proposed work.

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, (4) Addendum for Technology/Knowledge Readiness Level Checklist,* ***(5) Current and Pending Support,*** *(6) Addendum for Extramural Research Involving Human Subjects, (7) Documentation of FDA Engagement, and Focus Area Specific Documentation.*

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 limits and/or the specified file size above may not be accepted. **Each document shall be uploaded to BIDS separately (see Attachment 7 of PPG for BIDS instructions).**

Enhanced White Papers **exceeding the page limit specified in this section of the RPP may not be accepted.**

FOR INFORMATION ONLY: Please note a full Cost Proposal will only 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 are subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided.

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 5 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. §4021, Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

5 Selection

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.

5.2 Enhanced White Paper Evaluation

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 cost proposal based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Enhanced White Papers against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all Enhanced White Papers will be evaluated based on the following factors. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

Evaluation Factor 1 – Programmatic Relevance: The Offeror's Enhanced White Paper will be assessed for how well the proposed prototype demonstrates alignment and relevancy to the RPP's Focus Areas of Interest described in Section 3 and overall military impact. The following information will be considered as part of this factor:

- **The Clinical Problem:** The degree to which the Offeror demonstrates an innovative approach/solution and demonstrates an understanding of the research gap described in the RPP.
- **Minimum Requirements for Submission of an Enhanced White Paper:** The Offeror's ability to clearly and completely demonstrate that the following minimum requirements (as detailed in Section 3.2) have been met or exceeded:
    - **Demonstrate Military Relevance:** The degree to which the proposal demonstrates relevance by proposing medical solutions to support readiness and care in future battlefield scenarios.
    - **Fit the prototype definition:** The degree to which the proposal describes a prototype as described in Section 3.2 of this RPP.
    - **Meet the Minimum KRL/TRL:** The Offeror's ability to (i) clearly demonstrate that the proposed project meets the minimum acceptable KRL/TRL requirement at the time of submission (KRL/TRL 3 or otherwise stated) and ii) adequately support the indicated KRL/TRL of the proposed project.
    - **Represent a New Submission:** Whether the proposal represents a new proposal to MTEC and is not an identical resubmission of a previously submitted proposal.
    - **Align to RPP:** The degree to which the proposed project meets the overall intent of this RPP and aligns to a single focus area of interest specified in Section 3.3.

Evaluation Factor 2 – Technical Approach: The Offeror's proposal will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The Government's evaluation of this factor may include the degree to which the following are addressed:

- Hypothesis and objectives;

- Scientific rationale with supporting preliminary data;
- Experimental design, feasibility, and risks;
- Ability for the technical and management team to execute the proposed SOW in an efficient and effective manner (to include addressing USAMRDC's Office of Human and Animal Research Protections Oversight approval requirements); and
- SOW and estimated budget.

Evaluation Factor 3 – Commercialization Readiness Advancement: The Offeror's proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Offeror's commercialization readiness, analogous to TRLs. Examples of the information that may be assessed **(if applicable to the proposed project):**

- **Technical Maturity Advancement:** The degree to which the Offeror proposes to advance the technical maturity level during the performance of the project and advance the technology to the next level of development, from a technical and financial perspective. As such, the Government may evaluate how well the funding strategy supports that advancement.
- **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.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

Table 2 explains the adjectival merit ratings that will be used for the Programmatic Relevance, Technical Approach and Commercialization Readiness Advancement 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.

Upon review of the Enhanced White Papers, Offerors who are favorably evaluated may be invited for informal discussions with the Government. Upon completion of the Stage 1 evaluations, Offerors may be selected for funding (receive an overall recommendation of "Award"), placed into the basket, or not selected. Selection of prototype projects is a highly competitive process and is based on the evaluation of the Enhanced White Paper's technical merit, programmatic considerations, and the availability of funds. Therefore, Enhanced White Papers that receive the highest merit ratings and thus demonstrating technical merit are not automatically recommended for funding as such decisions consider funding priorities and how to best achieve program objectives. All Offerors will receive feedback to include a summary of the technical evaluation for their proposal submission. Additionally, Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 4.3 for additional instructions and Addendum 5 for details regarding the anticipated Stage 2 evaluation. Offerors are advised that, due to the anticipated high number of Enhanced White Paper submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback.

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.

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. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
ADSM	Active-Duty Service Member
AF	Air Force
AI/ML	Artificial Intelligence/Machine Learning
AOME	Air Force Aerospace and Operational Medicine Enterprise
ATI	Advanced Technology International
BATDOK	Battlefield Assisted Trauma Distributed Observation Kit
BCI	Brain Computer Interface
BHO	Behavioral Health Officers
BLA	Biologics License Application
CCCRP	Combat Casualty Care Research Program
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DoD	Department of Defense
DODEA	Department of Defense Education Activity
DODI	Department of Defense Instruction

FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
GMP	Good Manufacturing Practice
GLP	Good Laboratory Practice
Government	U.S. Government, specifically the DoD
HPD	Hearing Protection Devices
HSM	Head Supported Mass
HW	Hardware
IACUC	Institutional Animal Care and Use Committee
ICH	International Conference on Harmonisation
IM	Information Management
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IT	Information Technology
KRL	Knowledge Readiness Level
M	Millions
MEDCOP	Medical Common Operating Picture
MIDRP	Military Infectious Disease Research Program
MHS	Military Health System
MOMRP	Military Operational Medicine Research Program
MPAI	Military Prototype Advancement Initiative
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OHARO	Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
OTA	Other Transaction Agreement
PAI	Pre-Approval Inspection
PD	Pharmacodynamics
PDF	Portable Document Format
PK	Pharmacokinetics
PMA	Premarket Approval
POC	Point-of-Contact
PoP	Period of performance
PPE	Personal Protective Equipment
PPG	Proposal Preparation Guide
PTSD	Post-Traumatic Stress Disorder
QSR	Quality System Regulation
ROM	Rough Order of Magnitude

RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Experts
SOW	Statement of Work
SW	Software
SWAP	Size, Weight, and Power
TCR	Temporary Cornea Repair
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USASOC	U.S. Army Special Operations 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]

UEI: [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 2 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]

Focus Area

- Indicate which focus area of interest this Enhanced White Paper is responding to [include only one area per submission], for example, **FA 1.1 - Blood Product Development**.

Programmatic Relevance

- 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.
- Describe the relevance of your proposed technology to the healthcare needs of military.
- Describe how the proposed technology meets the definition of a prototype as defined in Section 3.2.
- Please indicate the KRL/TRL stage of the proposed solution at the time of submission of the Enhanced White Paper, as well as anticipated KRL/TRL at project completion. Full definitions of TRLs can be found here. More information regarding KRLs can be found here.

  KRL/TRL at Time of Submission:
  KRL/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 both the feasibility of proposed work and the indicated TRL/KRL. Please reference the TRL definitions for further information regarding expected scope of work for advancement toward the next TRL.
- 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.
- If you are proposing clinical research and/or trials, then please briefly describe your technical approach here in the Enhanced White Paper but include full details in Addendum 2 – Extramural Research Involving Human Subjects.

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

- [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 of each proposed follow-on task.
- Briefly outline the proposed methodology **by task** to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP.
- Indicate the proposed PoP (duration) for the potential follow-on work in total.
- Specify a total cost (including directs and indirects) for each task.

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 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) but include full details in Appendix 6 – Documentation of FDA Engagement.
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- 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.

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 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.

	Year 1	***Year 2***	***Year 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*		***$ 300,000.00***
Labor Hours	*1,000.0 hrs*		*1,000.0 hrs*	***3,000.0 hrs***
Subcontractors	*$ 50,000*		*$ 50,000.00*	***$ 150,000.00***

EXAMPLE

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*	*$ 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 (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 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. 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 with unlimited data rights.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 4: Technology/Knowledge Readiness Level Checklist (template provided in Addendum 1 of this RPP)

- The Offeror shall complete and submit the appropriate TRL checklist as a separate attachment depending on whether the technology qualifies as a knowledge product, pharmaceutical (drug), pharmaceutical (biologic/vaccine), medical device, or medical IM/IT or medical informatics. Note that all checkboxes must be checked up to and within a TRL in order for your technology to be considered at that TRL.

Appendix 5: Current and Pending Support (template provided in Addendum 4 of this RPP)

- Summarize other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request.

Appendix 6: Extramural Research Involving Human Subjects (template provided in Addendum 2 of this RPP). *This is only required if proposing a clinical trial*.

- If extramural research involving human subjects (clinical research, clinical trials) is proposed as part of your Enhanced White Paper, then include this addendum as a separate appendix to the submission. Human Subjects research should be described in adequate detail to address the study population and access to the population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, study variables/assessments/instruments, stats/data analysis etc. In addition, this addendum should address conformance with applicable regulations, guidance, and the requirements for potentially FDA regulated products. Alternatively, if available, the Offeror is highly encouraged submit draft clinical protocol documents intended for IRB review. Additional information related to the definition of human subjects research can be found here. However, if you have a specific question or need

clarification, we encourage you to reach out to the Points of Contact listed in Section 6 of this RPP for further discussion.

Appendix 7: Documentation of FDA Engagement (no template provided)

- *This is highly encouraged for Offerors who are proposing technologies that ultimately require approval or clearance by the U.S. FDA. Offerors are encouraged to demonstrate evidence of prior engagement with the U.S. FDA, for example, meeting minutes, evidence of submissions, FDA feedback documentation, etc.*

Appendix 8: Letter of Support (no template provided). *This is only required if proposing to Focus Area 1.12*.

- Letters of Support for Focus Area 1.12 should provide documentation of the following: 1) Ability to conduct work within Ukraine without U.S. personnel entering the country; 2) Evidence of a capable Ukrainian partner and any necessary support from the Ukraine Ministry of Health or Ministry of Defense; and 3) Where appropriate, a clear plan for necessary regulatory, ethics, and human protections approvals within the U.S. and Ukraine.

Appendix 9: Letter of Support (no template provided). *This is only required if proposing to Focus Area 3.8 or 3.10*.

- Letters of Support for Focus Areas 3.8 and 3.10 should be from a U.S. military commanding officer stating access to and participation of an ADSM population in the proposed solution.

Appendix 10: Biographical Sketches (template provided in Addendum 3 of this RPP). *This is only required if proposing to Focus Area 3.13*.

- Provide a biographical sketch for all key personnel contributing to the proposed work.

Addendum 1 – Technology/Knowledge Readiness Level Checklist

TRLs provide a systematic way to assess and communicate the level of maturity of a particular technology or combination of technology as it relates to product development across different types of technologies. Full definitions of TRLs can be found here. More information regarding KRLs can be found here. Offerors must submit the applicable checklist below as a separate appendix (see Section 8). As various types of proposed prototypes may be submitted under the 24-01-MPAI, the Offeror shall use only the appropriate checklist that aligns with the type of prototype outlined below:

- Checklist 1: Knowledge Products
- Checklist 2: Pharmaceutical (Drugs)
- Checklist 3: Pharmaceuticals (Biologics, Vaccines)
- Checklist 4: Medical Devices
- Checklist 5: Medical IM/IT & Medical Informatics

Note that all checkboxes within a KRL/TRL (and all previous KRL/TRL rows) must be checked for your technology to be considered at that KRL/TRL (i.e., if you are at a TRL 4, all boxes for TRLs 1-4 must be checked).

Checklist 1: Knowledge Readiness Levels – Knowledge Products	
KRL	**Checklist – *The Offeror must check all boxes up to and within each section/row to be considered at that KRL.***
1	☐Generate initial or very early scientific knowledge without regard to or indication of a specific health issue.
2	☐Expand on KRL 1 finding.
3	☐Validate hypotheses that suggest applications (e.g., prediction for prognosis, screening for diagnosis, or treatment for prevention).
4	☐Generate early or very early knowledge for some health-related use.
5	☐Test *a priori* hypotheses using rigorous scientific design. ☐Directly assess whether and how a tool can work.
6	☐Replicate optimally designed KRL 5 studies. ☐Assess for whom, under what conditions, and with what frequency a tool can serve in important applications.
7	☐Conduct early studies adapting KRL 4-6 research-supported applications for use in an identified context.
8	☐End on or replicate KRL 7 studies to directly assess whether the tool works in the context of interest.
9	☐Replicate or review optimally designed KRL 7-8 studies.

Checklist 2: Technology Readiness Levels – Pharmaceuticals (Drugs)	
TRL	**Checklist** – ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies. ☐Initiate and assess scientific literature reviews and initial market surveys.
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.
3	☐Perform basic research, data collection, and analysis begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate technologies supporting drug development. ☐Perform initial synthesis of countermeasure candidate(s) and identify their sites and mechanisms of action. ☐Perform initial characterization of candidate(s) in preclinical studies. ☐Demonstrate initial proof-of-concept for candidate drug constructs in a limited number of *in vitro* and *in vivo* research models.
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of candidate drugs (e.g., formulation, route(s) of administration, method of synthesis, physical/chemical properties, metabolic fate and excretion or elimination, and dose ranging). ☐Evaluate candidate in defined animal model to identify/assess potential safety and toxicity problems, adverse events, and side effects. ☐Identify assays to be used during nonclinical and clinical studies in evaluating candidate drugs.
5	☐Perform both nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate pharmaceuticals. ☐Results provide the basis for a manufacturing process amenable to cGMP-compliant pilot lot production. ☐Conduct GLP safety and toxicity studies in animal model systems. ☐Identify endpoints of clinical efficacy or its surrogate. ☐Conduct studies to evaluate the pharmacokinetics and pharmacodynamics of candidate drugs and initiate stability studies. ☐Results provide sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an IND application.
6	☐Hold pre-IND meeting (Type B) with CDER. ☐Prepare and submit IND. ☐Conduct Phase 1 clinical trials to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Evaluate pharmacokinetic and pharmacodynamic data to support the design of well-controlled, scientifically valid Phase 2 studies. ☐Demonstrate production technology through production-scale cGMP plant qualification. ☐Data from Phase 1 trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies.
7	☐Conduct and complete Phase 2 clinical trials to demonstrate initial efficacy and capture further safety and toxicity data. ☐Determine product activity (e.g., preliminary evidence of efficacy). ☐Determine product final dose, dose range, schedule, and route of administration established from clinical PK and PD data. ☐Present and discuss data with CDER at pre-Phase 3 meeting (Type B) to support continued drug development. ☐Determine clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CDER. ☐Obtain approval for Phase 3 clinical study plan or surrogate test plan.
8	☐Implement expanded Phase 3 clinical trials or surrogate tests to gather data on the safety and effectiveness of the candidate drug. ☐Conduct trials to evaluate the overall risk-benefit of administering the candidate, and to provide an adequate basis for drug labeling. ☐Complete process validation followed by lot consistency/reproducibility studies. ☐Hold pre-NDA meeting (Type B) with CDER, prepare NDA and submit to CDER, and gain approval of the NDA for the drug by CDER. ☐Complete facility pre-approval inspection (PAI).
9	☐The pharmaceutical can be marketed and distributed.

Checklist 3: Technology Readiness Levels – Pharmaceuticals (Biologics, Vaccines)	
TRL	**Checklist –** ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies. ☐Initiate and assess scientific literature reviews and initial market surveys.
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.
3	☐Perform basic research, data collection, and analysis begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate critical technologies and components supporting candidate biologic/vaccine constructs research and eventual development of a candidate countermeasure. ☐Conduct agent challenge studies to support models based on presumed battlefield conditions. ☐Initiate and evaluate research-scale process. ☐Identify sites and mechanisms of action, potential correlates of protection for vaccines, and physical/chemical characterization of biologic/vaccine constructs. ☐Demonstrate initial proof-of-concept for biologic/vaccine constructs in a limited number of *in vitro* and *in vivo* research models.
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of critical technologies for effective integration into candidate biologic/vaccine constructs, for example, environmental milieu (pH, adjuvant, stabilizers and preservatives, buffers, etc.), route(s)/methods of administration, proposed production/ purification methods, further physical/chemical characterization, metabolic fate and excretion or elimination, dose ranging, and agent challenge studies for protection. ☐Evaluate candidate biologic/vaccine in defined animal model to identify/assess safety and toxicity, biological effects, adverse effects, and side effects. ☐Identify assays, surrogate markers, and endpoints to be used during nonclinical and clinical studies to evaluate and characterize candidate biologic/vaccine constructs are identified.
5	☐Perform both nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate biologics/ vaccines produced and further development of selected candidates. ☐Results support proposing a potency assay, proposing a manufacturing process amenable to cGMP-compliant pilot lot production, identifying and demonstrating proof-of-concept for a surrogate efficacy marker in an animal model(s) applicable to predicting protective immunity in humans, and demonstrating preliminary safety and efficacy against an aerosol challenge in a relevant animal model. ☐Conduct GLP safety and toxicity studies in animal model systems. ☐Identify clinical efficacy endpoints or its surrogate in animal models that may be applicable to predicting protective immunity in humans. ☐Conduct studies to evaluate immunogenicity, as well as PK and PD when appropriate and initiate stability studies. ☐Results provide sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.
6	☐Hold pre-IND meeting (Type B) with CBER. ☐Prepare and submit IND. ☐Conduct Phase 1 clinical trials to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Evaluate immunogenicity and/or PK and PD data to support the design of Phase 2 clinical trials. ☐Validate surrogate efficacy models. ☐Data from Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical trials.
7	☐Conduct and complete Phase 2 safety and immunogenicity trials. ☐Determine product immunogenicity and biological activity (e.g., preliminary evidence of efficacy). ☐Determine product final dose, dose range, schedule, and route of administration established from vaccine immunogenicity and biologic activity, and when necessary, clinical PK and PD data. ☐Present data to CBER at pre-Phase 3 (or surrogate efficacy) meeting (Type B) to support cont. development of the biologics/vaccines. ☐Determine clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CBER. ☐Obtain approval for Phase 3 clinical study plan or surrogate test plan.
8	☐Implement expanded Phase 3 clinical trials or surrogate tests to gather data on the safety/effectiveness of the biologics/vaccines. ☐Conduct trials to evaluate the overall risk-benefit of administering the candidate, and to provide an adequate basis for product labeling. ☐Complete process validation followed by lot consistency/reproducibility studies. Hold pre-BLA meeting (Type B) with CBER, prepare BLA and submit to CBER, and gain approval of the BLA for biologics/vaccines by CBER. ☐Complete facility pre-approval inspection (PAI).
9	☐The pharmaceutical can be marketed and distributed.

Checklist 4: Technology Readiness Levels – Medical Devices		
TRL	**Checklist – *The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***	
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies and initiate initial market surveys.	
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.	
3	☐Perform basic research, data collection, and analysis to begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate component technologies. ☐Conduct initial tests of the design concept and evaluate candidate(s), define study endpoints, and propose animal models (if required). ☐Perform design verification and identify critical component specifications. ☐Develop tests (if a system component, or necessary for device test and evaluation). ☐Demonstrate initial proof-of-concept for device candidates in a limited number of laboratory models (may include animal studies).	
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). ☐Evaluate candidate devices/systems in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. ☐Identify procedures and methods to be used during nonclinical and clinical studies in evaluating candidate devices/systems. ☐Initiate the design history file, design review, and, when required, a master device record, to support either a 510(k) or PMA.	
5	510(k)	☐Determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection. ☐Preliminary findings suggest the device will be substantially equivalent to a predicate device.
	PMA	☐Compare devices to existing modalities and indications for use and equivalency demonstrated in model systems (e.g., devices tested through simulation, in tissue or organ models, or animal models if required). ☐Identify and qualify all component suppliers/vendors. ☐Audit all vendors for critical components for cGMP/QSR compliance. ☐Verify component tests, component drawings, design history file, design review, and any master device record. ☐Draft Product Development Plan. ☐Hold pre-IDE meeting with CDRH and prepare and submit IDE; review by CDRH determines the investigation may begin.
6	510(k)	☐Update and verify component tests, component drawings, design history file, design review, and any master device record. ☐Finalize preparation of manufacturing facility ready for cGMP inspection. ☐Information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in a military operational environment.
	PMA	☐Conduct clinical trials to demonstrate safety of candidate Class III medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Update and verify component tests, component drawings, design history file, design review, and any master device record. ☐Demonstrate production technology through production-scale cGMP plant qualification. ☐Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and supports proceeding to clinical safety and effectiveness trials.
7	510(k)	☐Produce final prototype and/or initial commercial-scale device and test in a military operational environment. ☐Information and data demonstrate substantial equivalency to predicate device and use in a military operational environment.
	PMA	☐Complete clinical safety and effectiveness trials with a fully integrated Class III prototype in an operational environment. ☐Continue study of effectiveness, and determine short-term adverse events and risks associated with the candidate product. ☐Complete functional testing of candidate devices, resulting in final down-selection of prototype device. ☐Complete final product design and produce final prototype and/or initial commercial scale device. ☐Collect, present, and discuss data with CDRH in support of continued device development. ☐Clinical endpoints and test plans agreed to by CDRH.
8	510(k)	☐Prepare and submit 510(k) application; approval of the 510(k) by CDRH has been received.
	PMA	☐Conduct trials to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. ☐Complete QSR compliance, the design history file, design review, and any master device record. ☐Device production followed through lot consistency and/or reproducibility studies. ☐Hold pre-PMA meeting with CDRH and complete facility pre-approval inspection (PAI). ☐Prepare and submit PMA application; approval of the PMA by CDRH has been received.
9	☐The medical device can be marketed and distributed.	

Checklist 5: Technology Readiness Levels – Medical IM/IT and Medical Informatics	
TRL	**Checklist** – ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Explore hardware (HW)/software (SW) System technology. Basic theories applied to IM/IT field suggest promise. ☐Identify the potential medical solution to mission need and define Medical Informatics data and knowledge representation issues.
2	☐Begin HW/SW Systems invention. ☐Document overall system concepts by flowcharting or other system descriptive techniques. ☐Define Medical Informatics data and knowledge representation schema.
3	☐Investigate and develop separate elements of HW/SW System components (not yet integrated or representative). ☐Model Medical Informatics data and knowledge representation schema.
4	☐Produce prototype. ☐Integrate HW/SW system components to establish that pieces will work together. ☐Instantiate Medical Informatics data and knowledge representation models with representative data or knowledge from applicable domain.
5	☐Test prototype in a laboratory environment. ☐Integrate HW/SW system components and employ realistic supporting elements so that the system can be tested in a simulated environment. ☐Specify actual interfaces to supporting systems and begin development. ☐Implement Medical Informatics data and knowledge representation models as data and/or knowledge management systems.
6	☐Perform advanced technical testing of prototype HW/SW System, to include interfaces to actual supporting systems in a relevant or simulated operational environment. ☐Outproduct is final prototype. ☐Test Medical Informatics data and knowledge management systems with target applications in a lab environment. ☐Develop configuration management.
7	☐Prototype HW/SW System is near or at planned operational system. ☐Demonstrate actual system prototype in an operational environment with end-users (first cut user test). ☐Operationally integrate and test Medical Informatics data and knowledge management systems with target applications in an operational environment.
8	☐Test and evaluate the HW/SW System in its intended environment to ensure that design specifications are met. ☐Validate fully integrated and operational Medical Informatics data and knowledge management systems in several operational environments. ☐HW/SW System has been proven to work in its final form and under expected conditions.
9	☐HW/SW System is in its final form and under mission conditions, such as those encountered in operational test and evaluation. ☐Medical Informatics knowledge maintenance and verification of data integrity are ongoing. ☐Military requirements met for transportation, handling, storage, etc. ☐Product successfully used during military mission as component of IOT&E phase. ☐Logistical demonstration successfully conducted.

Addendum 2 – Extramural Research Involving Human Subjects

If this Enhanced White Paper involves the participation of human subjects and is conducted solely by a non-federal entity, then include this addendum as a separate appendix to the submission. Human research should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of drugs, biologics, or dietary supplements. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997).]. Use the template provided below. This Addendum is limited to ten (10) pages and must be in 12-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Additional information related to the definition of human subjects research can be found here. However, if you have a specific question or need clarification, we encourage you to reach out to the Points of Contact listed in Section 6 of this RPP for further discussion.

Continuation

- If the proposed clinical research and/or trials were initiated using other funding prior to this application, explain the history and background of the study and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.
- If the proposed clinical research and/or trials involves continuation or assumption of an ongoing effort then state the transition plan proposed (e.g., transfer of FDA Sponsorship). In the case of ongoing clinical trials, append or provide reference to previous FDA-regulated studies. Offeror must justify carefully any changes proposed to ongoing FDA-regulated protocols and provide specific rationale for alterations (e.g., FDA feedback, change in clinical resources or study sites, etc.)

FDA Interactions

- Describe plan to meet all regulatory sponsor responsibilities under ICH parts E6, E2A, E8, and 21 Code Federal Regulation parts 312, 11, 50, 54, 56 including regulatory writing and submissions support for clinical efforts, safety reporting, pharmacovigilance, clinical monitoring, data management, regulatory writing and submissions, etc.]

Test Materials

- Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested and the projected outcomes or measures.
- Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
- Describe the production/manufacturing plan for the test materials proposed.

Study Design/Clinical Protocol

- Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential risks and challenges and alternative strategies.
- Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random). This description shall include the composition of the proposed study population in terms of sex/gender, race, and ethnic group, and an accompanying rationale for the selection of subjects.
- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- Describe all study primary and secondary endpoints.

Statistical Plan and Data Analysis

- Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of human samples to be studied.
- If multiple study sites are involved, state the approximate number to be enrolled or samples collected at each site.
- Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- If a subpopulation of a sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.

Technical Risks

- Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.

Ethical Issues

- Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.

Training/Proficiency Requirements

- Describe your plan to ensure that personnel have appropriate training/competency.

Study Timeline/Schedule

- Describe the study timeline/schedule, including visits/follow-up. *See the example below.*

Schedule of Study Visits Example*				
	Visit 1 (Month #)	Visit 2 (Month #)	Visit 3 (Month #)	Visit 4 (Month #)
Informed Consent	X			
Medical History	X			
Complete Physical Exam	X			
Abbreviated Physical Exam		X	X	X
Height	X	X	X	X
Weight	X	X	X	X
Vital Signs	X	X	X	X
Pharmacokinetics		X		
Randomization	X			
Administration of Study Drug	X	X	X	X
Counting of Returned Study Drug		X	X	X
Concomitant Medication Review	X	X	X	X
Adverse Experiences	X	X	X	X

**This above table is meant to provide an example. Add columns and/or rows as necessary.*

Addendum 3 – Biographical Sketch

Biographical Sketch

<table>
<tr><td colspan="4">Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form</td></tr>
<tr><td colspan="2">NAME</td><td colspan="2">POSITION TITLE</td></tr>
<tr><td colspan="4">EDUCATION/TRAINING (Begin with Baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)</td></tr>
<tr><td>INSTITUTION AND LOCATION</td><td>DEGREE (IF APPLICABLE)</td><td>YEAR(S)</td><td>FIELD OF STUDY</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.</td></tr>
</table>

Addendum 4 – Current and Pending Support

CURRENT
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

PENDING
Solicitation Number:
Title:
Funding Agency/Requiring Activity:
Proposed Period of Performance:
Proposed Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

Solicitation Number:
Title:
Funding Agency/Requiring Activity:
Proposed Period of Performance:
Proposed Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

PREVIOUS (award period of performance ending within the past 5 years)
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

PERTAINING TO THIS PROPOSAL SUBMISSION:
Title:
Proposed Period of Performance:
Proposed Costs (ROM):
Organization's Role:
Key Personnel (Name, Role, Citizenship, Current Country of Residence, Time Commitments):
Brief summary of the scope of work:

1. Is the applicant wholly owned in a non-U.S. country?

   ☐ Yes ☐ No

   If yes, disclose the non-U.S. country: _____

2. Has the applying organization, or any individual within, received direct or indirect support (including but not limited to in-kind contributions, grants and contracts that have ended up to 5 years ago) associated with participation in programs sponsored by non-US governments, instrumentalities, or entities, including foreign government-sponsored talent recruitment programs? **Note, "Foreign government-sponsored talent recruitment program" is defined as an effort organized, managed, or funded by a non-US government, or a non-US government instrumentality or entity, to recruit science and technology professionals or students (regardless of citizenship or national origin, or whether having a full-time or part-time position).**

   ☐ Yes ☐ No

If yes, in accordance with National Security Presidential Memoranda-33, describe and disclose the non-U.S. governments, instrumentalities, or entities below.

List all positions and scientific appointments, both domestic and foreign, held by senior/key personnel that are relevant to this proposal submission, including affiliations with foreign entities or governments. This includes the PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they request salaries or compensation.

Also identify all research resources including, but not limited to, foreign financial support, research or laboratory personnel, laboratory space, scientific materials, provision of high-value materials that are not freely available (biologics, chemical, model systems, technology, etc.), selection to a foreign "talents" or similar-type program, or other foreign or domestic support.

Resource/Lab Personnel & Space/Materials	**Foreign Affiliation**

Certification Regarding Disclosure of Funding Sources. The proposing organization must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;
- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and
- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

Signature

_____ _____

Signature of authorized representative of proposing Prime Contractor Date

Addendum 5 – 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) **Fairness and Reasonableness**. The Offeror’s cost proposal will be evaluated to determine if it is fair and reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

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

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