Request for Project Proposals

Solicitation Number: MTEC-25-04-MultiTopic

"Fiscal Year 2025 Multi-Topic Request for Project Proposals"

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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for the
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Noon Eastern Time Zone

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC), the Defense Health Agency (DHA), 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.

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 and DHA awarded under the authority of 10 USC § 4022. 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. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. For more information on the prototype definition, please see the Proposal Preparation Guide (PPG) located on the MTEC Members Only Site: https://private.mtec-sc.org/

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] (e.g., medical devices, drugs, and biologics). Military relevance is a key feature of this RPP.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC, in partnership with the Government, is utilizing a streamlined solicitation approach for this broad, multiple focus area RPP aimed at soliciting and funding a wide range of projects of varying scope and maturity levels. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. Several beneficial features of this solicitation approach include a long open window for proposals to be submitted, rolling evaluations of submitted proposals, and a diverse

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

roster of military sponsors interested in soliciting for key areas to support achievement of the military's medical strategic objectives.

Offerors who submit proposals, also called 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.

Awards may be made on a first-in, first-out basis. Additionally, the MTEC selection process for this solicitation includes a "basket" provision which allows for a means to identify those proposals with technical merit and warrant further consideration, however funding is currently unavailable. The proposals placed in the basket are eligible for funding for two years after date of submission.

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

2.2. Funding Availability and Period of Performance (PoP)

Due to the wide variety and inherent diversity of focus areas being solicited for in this RPP, the funding amount, expected PoP, number of anticipated awards, and timing of funding availability for each focus area is outlined briefly below and again in **Section 3.3 of this RPP**. The funding amounts and the number of expected awards will be limited and is contingent upon the availability of federal funds for each program. The estimated total available funding per focus area is as follows:

Focus Area 6 – Musculoskeletal Injury: The government anticipates making multiple awards for this focus area. Awards for research studies (other than those for clinical research) are anticipated to be ~$750K with a PoP not to exceed 36 months. Awards for clinical research studies are anticipated to be ~$3M with a PoP not to exceed 48 month. These awards are likely to be made with FY26 funding.*

Focus Area 7 – Quick Sterilant for Stainless Steel Medical Instruments: The government anticipates having ~$2M total for one or two awards with a PoP not to exceed 24 months.*

Focus Area 8 - Sensory Systems: The government anticipates making **up to** eight (8) awards of approximately $2M each with PoP not to exceed 24 months. These awards are likely to be made with both FY25 and FY26 funding.*

Focus Area 9 – Intracranial Pressure Monitor: The government anticipates having ~$5M total for one or two awards with a PoP not to exceed 36 months.*

Focus Area 10 - Precision Nutrition Development: The government anticipates making a single award with a PoP not to exceed 36 months.

Focus Area 11 – Vector-Based Surveillance: The government anticipates making a single award of ~$3-4M with a PoP not to exceed 36 months.*

*NOTE: these funding amounts are subject to change and represent the total available funding for the specified Focus Area and would include both direct and indirect costs.

Focus Areas 1, 2, 3, 4, 5, and 10: The government is unable to identify the funding availability for these focus areas and/or has not specified an estimated period of performance.

Offerors are encouraged to propose budgets and PoP 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 value of MTEC awards for an initial PoP is approximately $2.0 – 3.5M over a 2-3-year PoP.

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 Government 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 2025 and 2026 under the authority of 10 U.S.C. § 4022.

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 of this RPP** 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 Stage 2 Supplemental Information). 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 Multi-Topic Proposers Conference 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 Proposal 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 interested Offerors provide a more complete team for this requested scope of work:

- **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. Please visit https://www.mtec-sc.org/m-corps/ for details on current partners
- **MTEC Database Collaboration Tool** to help identify potential teaming partners among other MTEC members. It can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website (https://private.mtec-sc.org/).
- **Teaming Connect** is a dedicated live, virtual teaming session to facilitate teaming specific to this RPP. Registration information and date/time will be sent to the MTEC membership via email and will be posted on the MTEC website.

2.7. Offeror Eligibility

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

2.8. Cost Sharing Definition

Cost sharing is defined as the non-Federal 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.* 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**. 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. Additionally, **Section 7.4 of the PPG** contains information on cost share definitions and directions for inclusion.

2.9. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of an RPA under the MTEC OTA shall pay MTEC an amount equal to 2% of the total funded value of each research project awarded. Such deposits shall be due no later than 90-days after the RPA is executed. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other federally-funded contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not "Members in good standing".

2.10. Intellectual Property and Data Rights

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.

2.11. Expected Award Date

Offerors should plan on the PoP beginning no sooner than 4 months after the submission deadline (unless specified above in **Section 2.2 of this RPP**; all dates are 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.

2.12. Anticipated Enhanced White Paper Selection Notification

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

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

3 Technical Requirements

3.1. Background

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. **Individual Focus Areas of Interest will note any superseding KRL/TRL requirements.** 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.

*NOTE: Offerors should note that some Focus Area topics specify different minimum TRL for solutions to be considered for funding. Full definitions of TRLs can be found here. More information regarding KRLs can be found here. See **Addendum 1** for a reference checklist to assist in assessing the TRL of the proposed project.

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 24-01-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. Additionally, proposals that fail to include all required documentation as

listed in Section 4.2 of this RPP may not be considered for funding., See Addendum 6 of this RPP which identifies the documents that are required and/or encouraged for each Focus Area.

Focus Area 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 minimum 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*
- 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 **required** 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)

Focus Area 2 - Pathogen Agnostic Countermeasures for the Treatment of Sepsis Caused by Wound Infection:
This focus area of interest seeks the 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.

Focus Area 3 - Antivirals for the Prevention and/or Treatment of Endemic and Emerging Infectious Diseases (Non-biothreat Pathogens):
This focus area of interest seeks the 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 specific to Africa and/or Asia (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
- 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.

Focus Area 4 - Prevention of Endemic Diarrheal Diseases:
This focus area of interest seeks the development of immunoprophylactics for endemic viral diarrheal diseases, with a focus on norovirus.

- 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.

Focus Area 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 5.1** - Decipher the intricate relationship between combat polytrauma, infections and sepsis for data-driven clinical practice guideline revisions and field medicine.
- **FA 5.2** – Modernize the effectiveness of acute traumatic wound management. Proposed projects shall 1) assess the effectiveness of the Acute Traumatic Wound Management guidelines and 2) optimize these guidelines to enhance the standard of care for traumatic wound infections 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 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 6 – Musculoskeletal Injury:
Musculoskeletal injuries are the number one threat to Warfighter readiness, resulting in approximately 2.4 million medical visits and 25 million limited duty days. In the training environment, musculoskeletal injury accounts for up to 80% of causes for a Service Member

being medically non-deployable significantly impacting overall combat lethality. In the deployed environment, non-battle injuries account for 30% of all medical evacuations, and more than 85% of Service Members medically evacuated for musculoskeletal injury do not return to theater. Prior musculoskeletal injury is one the biggest predictors of future musculoskeletal injury and approximately half of Service Members can expect to sustain a new musculoskeletal injury each year.

The intent of this Musculoskeletal Injury Focus Area is to find solutions of high relevance to, and focused on, the Warfighter that have the potential to be applied closer to the operational environment. For the purposes of this funding opportunity, musculoskeletal injury care encompasses multiple domains including musculoskeletal injury risk identification and mitigation; initial interventions that improve survivability and maximize ability to stay in the fight pending evacuation to definitive care; and optimization of post-musculoskeletal injury outcomes.

Specific Requirements:
Proposed solutions must address one of the following (**not listed in order of importance**):

- **Focus Area 6.1 -** Screening tools and/or strategies to mitigate the risk of musculoskeletal injury (applied and clinical research studies permitted)
- **Focus Area 6.2 -** Interventions or programs to mitigate the incidence and/or severity of musculoskeletal injury (clinical research studies only)
- **Focus Area 6.3 -** Diagnostic solutions (material and/or knowledge products) for musculoskeletal injury in forward-deployed service members in denied, intermittent, or low-signal environments to enable care beyond their standard training or scope of practice (applied and clinical research studies permitted)
- **Focus Area 6.4 -** Scalable and rapidly deployable materiel solutions to support forward treatment of MSKI and reduce impact of MSKI on operational effectiveness (applied and clinical research permitted)
- **Focus Area 6.5 -** Rehabilitation interventions to accelerate recovery from musculoskeletal injury in the pre-hospital environment or preserve musculoskeletal health in the pre-hospital environment to optimize outcomes once definitive care is received. (applied and clinical research studies are permitted)

Inclusion of preliminary and/or published data relevant to the proposed research is **required**. Solutions that are broadly applicable across different types of musculoskeletal injuries are encouraged, when appropriate.

Proposed projects for other than those for clinical research may range from refinement of concepts into potential materiel or knowledge product solutions or tools or the maturation or down-selection of potential solutions. Proposed projects for clinical research may range from small proof-of-concept trials (e.g., pilot, first-in-human, phase 0) to demonstrate the feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant patient populations.

Applicants are encouraged to include option periods beyond the scope or budget of the project for anticipated next-stage efforts.

Additional Considerations

- Solutions proposed should be highly relevant to the military environment or injuries sustained by the military that would not be logically addressed by other funding agencies. For example, if the course of clinical care or the clinical practice guidelines would not differ in the military setting compared to a civilian setting, these solutions are unlikely to be prioritized.
- Solutions requiring the expertise of a surgical care team would be out of scope for this solicitation.
- App-focused solutions, solutions requiring cloud-based solutions, or solutions requiring prolonged use of wearable sensors are outside the scope of this solicitation.
- Patient populations with musculoskeletal injuries seen in high volume in the military but not prioritized in this solicitation include, but are not limited to, osteoarthritis, anterior cruciate ligament reconstruction, and rotator cuff repair.
- Additionally, solutions expanding an "understanding" of work in an area, without paths to clinical translation, are likely insufficient to meet the intent of this solicitation.
- If proposed solutions (both knowledge and material products) are at a TRL 5 or higher, then it is highly encouraged that offerors provide a letter of support from an entity or organization within the military that indicate willingness to serve as a transition partner.
- Letters of support from end users are highly encouraged.
- When appropriate (e.g. gaining access to relevant populations, stages of training, etc.), partnering with DoD collaborators or sites may be encouraged.

Focus Area 7 – Quick Sterilant for Stainless Steel Medical Instruments

Future battlefield scenarios may require a chemical sterilant that can sterilize quickly, safely, and without power. In particular, there is a need to sterilize surgical, medical, or laboratory tools within ten (10) minutes using non-toxic chemicals and non-hazardous disposal methods. Solutions to this focus area are intended to provide sterilization capability to medical roles and teams that lack or have limited access to electrical power, indoor plumbing, and transportation.

Many commercially available liquid chemical sterilant require multiple hours of soaking to achieve sterilization. Additionally, current steam sterilizers can be logistical burdens because they require power, plumbing, and have long sterilization cycle times. It is expected that the development of new chemical sterilization techniques will increase throughput of sterilizing tools between procedures, supporting surgical teams in large-scale combat operations and austere environments.

The intent of this focus area is to develop an FDA-cleared and Environmental Protection Agency (EPA)-registered chemical sterilant that can sterilize stainless steel medical instruments and/or

critical medical devices without power in less than 10 minutes, when used at or above its Minimum Recommended Concentration at ambient temperature.

Specific Requirements:
Proposed solutions should aim to expand or amend a current agency-approved sterilization indication to one that achieves sterilization within 10 minutes of immersion or exposure to the sterilant, without power requirements. Offerors are able to propose solutions where the existing FDA or EPA indication is for chemical sterilization or high-level disinfection. Proposed solutions could include development of a novel, quick sterilization technology if no current FDA sterilization indication exists.

The overarching deliverables for this effort would include:

1) Technical demonstration the product can achieve and maintain Sterility Assurance Levels (SAL) of $\log 10^{-6}$ in less than 10 minutes to support a sterilization indication.
2) Submissions to FDA or EPA to expand or amend existing indications, or for a new indication.
3) Development of a method to keep tools sterile after immersion or exposure to sterilant.

*The following information or documentation is **required** at time of proposal submission*

1) FDA approval number, indication, and instructions for use.
2) EPA registration number, indication, and instructions for use.
3) Description and dimensions of product and packaging.
4) Benchtop, independent, or Good Laboratory Practices (GLP) testing reports demonstrating SAL.
5) ISO/ANSI/AAMI tests completed (e.g., cytotoxicity, dermal irritation, stability, rinsability).
6) Package testing and product specifications.

Additional Considerations:

- Solutions that require power or use hazardous chemicals are out of scope for this effort.
- Offerors are encouraged to elaborate upon their capabilities by providing the following:
    - Demonstration of manufacturing capability.
    - Marketing and commercialization strategy.

Focus Area 8 - Sensory Systems

The DHA Sensory Systems Program focuses on military related injury or illness to sensory systems including research to characterize basic mechanisms and to advance assessment, diagnosis, monitoring, and treatment.

The Sensory Systems Program is organized into modalities of Auditory, Ocular, Pain, and Vestibular to encompass multiple distinct components of sensory medical S&T research. The program is intended to inform and describe DoD medical capabilities focused on injury or illness to sensory systems, including research to characterize basic mechanisms and to advance assessment, diagnosis, monitoring, and treatment.

Proposed solutions must address one of the following (**not listed in order of importance**):

- **Focus Area 8.1 - Improved pain control or anesthesia:** To develop and evaluate advanced pain control and anesthesia techniques that can be effectively utilized in military settings, enhancing pain management for injured service members both on the battlefield and in medical facilities.
- **Focus Area 8.2 - Ocular Injury Stabilization:** To develop a stabilization solution for ocular open-globe injury at the Point of Injury (POI).
- **Focus Area 8.3 - Tools and solutions to understand and access auditory injury:** The identification and/or development of improved hearing-protection and communication-enhancement devices is critical to maintaining and improving individual warfighter effectiveness, along with improved clinical testing methods and new predictive screening models. This research focus seeks to 1) Characterize, 2) Assess and 3) Prevent auditory injury for the maintenance or improvement of warfighter effectiveness.
- **Focus Area 8.4 - Ocular Injury assessment**: Develop and validate advanced diagnostic tools and techniques for the assessment of ocular injuries sustained in combat environments. This includes identifying and quantifying the severity of injuries, as well as guiding treatment decisions and monitoring recovery.
- **Focus Area 8.5 - Ocular Injury Treatment**: To advance the development of treatment solutions for ocular injures sustained by military personnel. This focus area will address both immediate and long-term damage caused by blunt trauma, blast injuries, penetrating wounds, and exposure to harmful military substances which are prevalent in combat environments. Ultimately, by focusing on cutting-edge and innovative treatment technologies, we aim to minimize vision loss, restore functional eyesight, and reduce the long term impact of ocular injuries on warfighter's quality of life and operational readiness.

Offerors are encouraged to include letters of support and/or proof of regulatory engagement within their proposal.

Focus Area 9 – Intracranial Pressure Monitor

Intracranial pressure (ICP) is a physiologic parameter that is indicative of proper brain health. Traumatic events to the head and brain can cause ICP to elevate, which can rapidly become life-threatening. Current standard of care for measuring and monitoring ICP are invasive and require penetrating the skull with a monitoring device; a surgical procedure typically performed by a neurosurgeon. Invasive surgical procedures introduce additional risks to casualties, which are exacerbated by austere field conditions and limited access to neurosurgical providers in combat operations. A capability to non-invasively and accurately measure and monitor ICP far-forward in the battlefield will inform the need for casualty evacuation (CASEVAC) and improve management of casualties over prolonged operations and where evacuation is not readily available/accessible.

The intent and scope of this Focus Area is the development of a field suitable, pre-hospital (Role of Care, or RoC, 1, 2, 3), non-invasive ICP monitor (though the use of surrogate markers or directly) with potential for integration with a total cranial vault hemorrhage detection device. There are multiple hemorrhage detection device candidates in development and independent from this proposal and solicitation. The Government does not intend to specify a single hemorrhage detection device as this selection may depend on Offeror's proposed solutions to this Focus Area. More information on the hemorrhage detection device may be provided if selected for award.

The following represent anticipated project management deliverables during the period of performance and shall be included in the Offeror's Statement of Work and Milestone Payment Schedule:

- The development, baseline, and maintenance of a project plan and integrated master schedule, inclusive of identified critical-path, milestones, and regulatory strategy
- The development, and maintenance of a project budget/spend plan depicting the execution of funds throughout the project and enabling traceability of funding to project deliverables

By the end of the period of performance, the technology must be at TRL 6 or higher, establish a proof of concept of integration with hemorrhage detection device, and include demonstration and delivery of a functional prototype.

Specific Requirements:

The Government's objective is to field an integrated capability that meets the technical specifications listed in Table 1 (below). By end of PoP, performer will demonstrate proof of concept that these goals are achievable with a prototype ICP candidate. It is not the intent of this proposal that the resulting technology meets/exceed these specifications by the end of the period of performance.

Table 1: Desired performance specifications for End-State Capability

Performance Parameter	Threshold	Objective

Regulatory Approval as a diagnostic/ assessment decision support tool	FDA Clearance/ Approval	
Moderate/ Severe TBI Assessment	Informs Brain Hemorrhage AND Elevated ICP	
Sustainability Operational Availability	>/= 90%	>/= 95%
Use on Unconscious and Conscious Casualties	Can be used on Unconscious Casualties	Can be used on Unconscious Casualties
Time parameters for results	5-10 minutes	</=5 minutes
Power	Standard (COTS) disposable battery	Rechargeable/ No Power
Interoperability, Net-Ready: Entered and managed on the network	Data transmission from device/analyzer from medical personnel at RoC 1 through the ITN to medical providers at higher echelons of care	
Hemorrhage detection	Detects and monitors (serial assessment) of hemorrhage size AND location, anywhere in the cranial cavity	
ICP Detection	Non-invasively detects and monitors (serial assessment) ICP with an accuracy of + 2mmHg for a range of 0-20 mmHg and a maximum error of 10% for pressures between 20-100 mmHg	
Sensitivity	>75%	>95%
Specificity	>75%	>95%
Portability (System Weight)	<10lbs	<5lbs
Portability (System Cube)	<3ft^3	<1ft^3
Storage Temperature	No Cold Chain Required	No Cold Chain Required
Temperature Use Ranges	20-90 °F	-20-125 °F
Stand-by Temperature	High Temperature Storage: 120 F for seven days Low Temperature Storage: 0 F for seven days	High Temperature Storage: >120 F for seven days Low Temperature Storage: <0 F for seven days
Humidity Use Ranges	Humidity cannot exceed 90%±2 RH at 25.0±2°C or be less than 30%±2 RH at 0.0±2°C.	Can be used in high humidity conditions (cycled between 95%±2 Relative Humidity (RH) at 29.5±2°C and 88%±2 RH at 41.0±2°C) IAW Joint Enroute Care Equipment Test Standard (JECETS). Can be used in low humidity conditions (20%±2 RH at 0.0±2°C

Salt Fog/Water Exposure	Device can withstand one cycle of 5 minutes of salt fog exposure and 5 minutes of drying (modified from MIL-STD 810G)	Device can withstand one cycle of 30 minutes of salt fog exposure and 30 minutes of drying (modified from MIL-STD 810G)
Ingress Protection Rating	IP54 or higher (protected against dust; protected against splashing water)	
Altitude:	Must be capable of operating at altitudes $\geq$ 8000 ft	
Complexity of Use	[Must be useable by 68W] Moderate complexity – some training; operation time (<20 min)	[Must be useable by 68W] Low complexity – minimal training; operation time (<15 min)

Additional Considerations:

- All proposed technologies must be TRL $\geq$4 prior to project award
- Offerors are encouraged to list optional tasks for future consideration
- Offerors are encouraged to include letters of support, proof of regulatory engagement, specific data sets used and proposed.
- Offerors are encouraged to include a comparison and advantages to other existing or past technologies in development
- The following solutions will be considered out of scope:
    - Invasive technologies
    - Technologies not capable of meeting the requirements in Table 1
    - Technologies that are not capable of utilization by field medics (68W)
    - Technologies that utilize expensive (>$100) consumables (Class VIII)
    - Technologies that require constant network access

Focus Area 10 – Precision Nutrition Development

Optimal nutrition is crucial for warfighters as it directly impacts their physical and cognitive performance, which is essential in high-stakes, demanding environments. Proper nutrition provides the energy and nutrients needed for physical endurance, helping warfighters maintain strength, stamina, and resilience during sustained training and/or combat operations. A balanced, well-timed diet supports muscle function, aiding in injury recovery, and helping to sustain performance under extreme conditions. It also fuels cognitive functions like decision-making, focus, and reaction time, ensuring that warfighters can remain sharp and effective in stressful, high-pressure situations.

In addition to enhancing immediate operational readiness, proper fueling plays a key role in long-term health and overall well-being. A well-rounded diet strengthens the immune system, reducing the risk of illness and injury, and supports mental health by helping to regulate mood and stress. Proper hydration and nutrient intake help warfighters adapt to challenging environments, from extreme heat to limited access to fresh food. Ultimately, delivering the right nutrients in the right amount to the right place at the right time and ensuring bioavailability of

the payload ensures that warfighters are physically prepared, mentally resilient, and able to perform at their best, thereby contributing to mission success and their long-term health.

This focus area aims to establish a pilot study for novel nutrition formulations designed to enable optimal physical and cognitive performance over an extended period of time. One goal of this effort would be to determine if optimizing, encapsulating, and extending the release of nutritional payloads found within the food and beverage products consumed by warfighters would have measurable performance benefits.

Offerors responding to this focus area are encouraged to provide solutions capable of:

- Targeted and time-controlled release and bioavailability enhancement through precision delivery of multiple macronutrients
- Utilizing Generally Recognized as Safe (GRAS) ingredients as potential excipients for modulating the release of energy substrates (macronutrients) for sustained payload release of at least 12 hours.

Specific Requirements:
Proposed solutions are expected to include (but are not limited to) the following characteristics and activities:

1. Manufacturing of nutritional formulations in food grade volumes suitable for consumption in human bioavailability and performance trials;

2. Macronutrient payloads, at a minimum, must include glucose, a protein source, glucose and a protein source, a fatty acid, and a ketone ester;

3. Assessing the bioavailability of the payloads in human subjects for a minimum of 12 hours;

4. Assessing the effectiveness of the payloads for improving physical and cognitive performance, gastrointestinal (GI) tolerability, satiety, acceptability, and military utility of the payloads in human subjects;

5. Must be able to provide evidence of previous in vitro studies demonstrating successful sustained release of the payloads over a 12-hour time period;

6. Must be able to provide evidence of previous in vitro studies demonstrating successful validation and optimization of GRAS ingredients as successful excipients in the release of the payloads.

Preliminary data using high-throughput screening of GRAS materials to create formulations capable of a minimum of 12-hour duration during in vitro simulation of the digestive tract is **required**.

Offerors are encouraged to include letters of support and/or proof of regulatory engagement within their proposal.

Focus Area 11 – Vector-Based Surveillance

United States military personnel live and work globally, sometimes in austere environments. This global presence increases the likelihood of exposure to emerging infectious diseases. Most emerging infectious diseases are zoonotic (transmitted from animals to humans), and disease transmission to humans is often facilitated by arthropod vectors. Effective medical countermeasures do not exist for many of these emerging infectious diseases, limiting the ability to prevent illness and control the transmission of disease. Microbial genomic surveillance using next generation sequencing is a tool that can be used to track pathogens as they evolve and spread, generating data necessary to mitigate the threat of large-scale outbreaks in immunologically naïve populations. Microbial genomic surveillance in global "hotspots" suspected of harboring emerging pathogens requires an established capability to rapidly process and data.

High quality, readily available data is necessary to provide risk analyses to inform military force health protection (FHP) recommendations. In order to produce timely, actionable data for FHP decision-makers, there is a need for: 1) standardized and easily deployable protocols for sampling the environment and arthropods for emerging pathogens, 2) robust laboratory sample processing and next generation sequencing methods and assays, 3) laboratory information and data management tools for real-time sharing of genomic data and other results, and 4) validated interfaces to transmit data from non-military laboratory partner information systems to military information systems.

This Focus Area aims to leverage standardized next generation sequencing (NGS) protocols for detection and characterization of militarily relevant zoonotic pathogens in arthropod vectors and environmental samples and using resulting data to produce actionable insights that can inform public health and force health decision-making.

Specific Requirements:

Proposed solutions should implement tools to better integrate data from environmental and arthropod vector samples for global surveillance of emerging infectious diseases. Using biosurveillance and xenosurveillance methods, as appropriate, data should be collected to develop risk assessments that will provide FHP decision makers with information needed to assess appropriateness and/or availability of medical countermeasures.

Along with a robust global laboratory sample collection and testing schema, a platform is needed for management, integration, and broad dissemination of information to appropriate Department of Defense personnel. This may involve coordination with multiple parties and

integration of data sources, would need to be consistent across implementing partner laboratories and integrated with larger DoD biosurveillance efforts.

Successful implementation of these solutions will require an understanding of DoD IT infrastructure and military FHP needs so that information dissemination is feasible and communicated in the correct context. Solutions should also be based upon identified knowledge gaps that can be filled through timely biosurveillance and/or xenosurveillance of emerging infectious diseases. Ultimately, any solutions should feed into a comprehensive data analysis pipeline and risk reporting process so that decision makers have the integrated information needed to take the proper precautions to ensure their health and readiness of Service Members.

Additional Guidance
Proposals submitted to this focus area are **required** to include the following tasks in addition to tasks that accomplish the specific requirements of this focus area:

- Conduct a post award conference meeting (e.g., kick off meeting) within 15 to 30 business days of award at the performer's location for up to 6-8 Government representatives. The performer shall coordinate the meeting date with the government and be able to accommodate additional participants by teleconference.
- Submit monthly technical data and status reports.
- Develop an Integrated Management Plan (IMP) and/or Integrated Management Schedule (IMS) for realistically plan and executable research.
- Develop laboratory protocols and testing plans, including:
  (a) SOPs for the surveillance protocol, laboratory protocols, test plans, as well as approach for management and dissemination of epidemiological and risk management information to appropriate decision-making DoD personnel.
  (b) Training materials for government personnel involved in the integration, reporting and decision-making processes to include confirmation that training was successfully completed.
- Develop Quality Management Programs to ensure compliance with all federal and DoD regulations, including:
  (a) Existing standard operating procedures for all sample types inclusive of updates and research reports derived from the sampling data.
- Provide access to the web-based dashboard and databases developed as part of the program as well as related IT updates to communicate data.
- Provide CX (Customer Experience) access to include updates to the system algorithms and full access to the website.

- Participate in scientific meetings, symposiums, and publications where the data from the work will be presented.

Additionally, offerors are **required** to detail a management approach for all major sub-contractors (including any proposed Government Laboratories) and include a biosketch of the Principal Investigator.

3.4. Additional Points of Consideration

- 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 refinement and 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 January 15th, 2025.** Include the MTEC Solicitation Number (**MTEC-25-04-MultiTopic**) 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-25-04-MultiTopic**). Note that full 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. **Current and Pending Support:** one Word of PDF document (**Attachment 5 of the PPG)**
5. **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**Attachment 6 of the PPG**)
6. **Technology/Knowledge Readiness Level Checklist:** one Word or PDF document (**Addendum 1 of this RPP**)

Supplemental Submission Documents (*as applicable to the proposed solution*): 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.* **This is specifically encouraged for solutions submitted to Focus Areas 1, 3 and 8.**

Focus Area Specific Submission Documents: In addition to the submission documents described above, several focus areas require additional documents. See Addendum 6 of this RPP which identifies the documents that are required and/or encouraged for each Focus Area. These documents shall be submitted via BIDS (5MB or lower):

- **Letters of Support:** one Word or PDF document (no template provided) from a relevant source regarding the proposed solution**.**

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

- **Published Data Addendum:** one Word or PDF document (no template provided) summarizing published literature, preliminary findings, and/or preclinical efficacy data related to the proposed solution. Inclusion of toxicity data is also encouraged for Focus Areas 1, 2, 3, and 4.

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) Current and Pending Support, (4) Intellectual Property and Data Rights, (5) Addendum for Technology/Knowledge Readiness Level Checklist, (6) Addendum for Extramural Research Involving Human Subjects, (7) Documentation of FDA Engagement, and (8) Focus Area Specific Submission Documents (i.e., Letters of Support, Biographical Sketches, and Published Data Addendum).*

The Enhanced White Paper and its Appendices must be in 12-point font (or larger), single-spaced, 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.**

Addendum 6 of this RPP contains a table indicating which documents are required or encouraged for each Focus Area.

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, the Government reserves the right to request additional attachments/appendices (henceforth referred to as Stage 2 Supplemental Information) to this proposal submission after completion of the technical evaluation. The exact requirements of any such attachment/appendix (i.e., Stage 2 Supplemental Information) 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 Stage 2 Supplemental Information, 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 allowable as a direct charge to any resulting award or any other federally-funded 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.

5.1 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 and in accordance with programmatic priorities and annual appropriations. 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.

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 relevancy 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 volume 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 Manager, Taylor Hummell, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Chuck Hutti, Ph.D., chuck.hutti@ati.org

- All other questions should be directed to the MTEC Program Manager, Evan Kellinger, mtec-sc@ati.org

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
API	Application Programming Interface
ATI	Advanced Technology International
BHO	Behavioral Health Officers
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
CMA	Consortium Member Agreement
COTS	Commercial of the Shelf
CPIC	Clinical Pharmacogenetics Implementation Consortium
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DHA	Defense Health Agency
DoD	Department of Defense
DODEA	Department of Defense Education Activity
DODI	Department of Defense Instruction
EHR	Electronic Health Record
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
GI	Gastrointestinal
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
Government	U.S. Government, specifically the DoD
GRAS	Generally Recognized as Safe
HW	Hardware
IACUC	Institutional Animal Care and Use Committee
ICP	Intracranial Pressure
IM	Information Management
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IT	Information Technology
JECETS	Joint Enroute Care Equipment Test Standard

KRL	Knowledge Readiness Level
M	Millions
MHS	Military Health System
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
MTF	Medical Treatment Facilities
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
PD	Pharmacodynamics
PDF	Portable Document Format
PGx	Pharmacogenomics
PK	Pharmacokinetics
PMA	Premarket Approval
POC	Point-of-Contact
POI	Point of Injury
PoP	Period of performance
PPE	Personal Protective Equipment
PPG	Proposal Preparation Guide
QSR	Quality System Regulation
RoC	Role of Care
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Experts
SOW	Statement of Work
SW	Software
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government

8 Enhanced White Paper Template

Cover Page

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

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, **Focus Area 1 - Prophylactic to Prevent Infection in Battlefield Wounds from Complex Traumatic Penetrating Injuries in a Far-Forward, Austere Environment** .

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*	*.00*	*$ 50,000.00*	***$ 150,000.00***
Subcontractors Hours	*.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***

EXAMPLE

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: Current and Pending Support (template provided in Attachment 5 of the PPG)

- 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. If there is no current and/or pending support, enter "None."

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

- The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights.
- 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 5: 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 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.

Focus Area Specific Submission Documents: In addition to the submission documents described above, several focus areas require additional documents. See Addendum 6 of this RPP, which identifies the documents that are required and/or encouraged for each Focus Area.

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).

Appendix 9: Biographical Sketches (template provided in Addendum 3 of this RPP).

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

Appendix 10: Published Data Addendum (no template provided).

- Summary of published literature, preliminary findings, and/or preclinical efficacy data related to the proposed solution.
- **Inclusion of toxicity data is also encouraged for Focus Areas 1, 2, 3, and 4.**

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 25-04-MultiTopic, 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:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

Pending
Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

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 (for only those proposals recommended for award) 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. If a proposal is selected for award, the MTEC CM will provide a formal assessment to the Government, at which time the Government will make the final determination of whether or not 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 represent what the cost of the project should be for the effort to be accomplished, assuming reasonable economy and efficiency. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will perform an analysis 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 based upon verifiable techniques such as estimates developed from applicable and relevant historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website. If the MTEC template is not used, the Offeror should submit a format providing for a similar level of detail.

c) **Completeness**. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

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

Negotiations
The Government anticipates entering negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

Addendum 6 – Required Submission Documents by Focus Area

This Addendum is intended to be a supplement for the information provided in **Sections 3.3 and 4.2**. Please refer to the below data to identify which documents are required (R), encouraged (E), or required if applicable to an offeror's proposed solution (RA). Should you have any questions, please reach out the points of contact listed in **Section 7 of this RPP**.

Focus Area	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Enhanced White Paper	R	R	R	R	R	R	R	R	R	R	R
Warranties and Representations	R	R	R	R	R	R	R	R	R	R	R
Statement of Work / Milestone Payment Schedule	R	R	R	R	R	R	R	R	R	R	R
Current and Pending Support	R	R	R	R	R	R	R	R	R	R	R
Intellectual Property and Data Rights Assertions	R	R	R	R	R	R	R	R	R	R	R
Technology / Knowledge Readiness Level Checklist	R	R	R	R	R	R	R	R	R	R	R
Extramural Research Involving Human Subjects	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA
Documentation of FDA Engagement	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA	RA
Letters of Support						E	E	E	E	E	E
Biographical Sketches											R
Published Data Addendum	R	R	R	R		R	R		E	R	R