Request for Project Proposals

Solicitation Number: MTEC-26-04-MultiTopic

"Fiscal Year 2026 Multi-Topic Request for Project Proposals"

Issued by:
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909 Ross Avenue
North Bethesda, MD 20852

Request Issue Date: August 6, 2026

Enhanced White Paper Due Date: October 30, 2026
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/Department of War (DoD/DoW), 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 www.mtec-sc.org

MTEC, Inc. is a 501(c)(3) non-profit corporation that operates the MTEC under an Other Transaction Agreement (OTA) for prototype projects with the Defense Health Agency (formerly the USAMRDC) awarded under the authority of 10 U.S.C. § 4022. The term "prototype project" includes a project that addresses (A) a proof of concept, model, or process, including a business process, (B) reverse engineering to address obsolescence, (C) a pilot or novel application of commercial technologies for defense purposes, (D) agile development activity, (E) the creation, design, development, or demonstration of operational utility, or (F) any combination 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 website at www.mtec-sc.org/proposal-submit.

1.2. Purpose

This solicitation 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)”) detailed in Section 3.3. 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

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 and time 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 deadline 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 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

Due to the wide variety and inherent diversity of focus areas being solicited for in this RPP, the funding amount, expected Period of Performance (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 10: Musculoskeletal Injury Treatment

- **Focus Area 10A: Therapeutic interventions to accelerate recovery from musculoskeletal injury,** the Government anticipates 1-2 awards of approximately $3M each with a PoP not to exceed 36 months.
- **Focus Area 10B: Preservation of Musculoskeletal Health,** the Government anticipates 2-3 awards of approximately $1.5M each with a PoP not to exceed 36 months.

Focus Area 15: Blast and Blunt Sensors for Exposure Monitoring, the Government currently has available a total of $10.5M for this topic, for direct and indirect costs in total. 2 awards are expected with a PoP not to exceed 48 months. 1 of these 2 awards may be up to $7M, for direct and indirect costs. These awards are expected to start in FY27.

*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, 6, 7, 8, 9, 11, 12, 13, and 14: Given the wide range of prototype maturity that could be responsive to these Focus Areas, the government wishes to keep funding availability unspecified and/or does not specify 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 size of MTEC awards for the 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 2027 and 2028 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 Government 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 supplemental information such as those examples listed under **Sections 4.2 and 4.3 of this RPP**). 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. MTEC 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 MTEC, 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 series that will be conducted via webinar(s) 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 series is to provide an administrative overview of this RPP process to award and to present further insight into the Focus Areas of Interest outlined in Section 3. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.5. Proprietary Information

MTEC will oversee submission of Enhanced White Papers submitted in response to this RPP. MTEC 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 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.

MTEC's new website features a new functionality to assist members in team building. To facilitate collaboration, MTEC members can utilize the Member Profiles directory to identify potential teaming partners, including technology innovators and specialized service providers. This resource is accessible via the MTEC portal at www.mtec-sc.org/members.

MTEC also intends to hold Teaming Connects for this effort, these will be virtual Teams meetings to help the membership collaborate and partner in relation to specific focus areas listed in the RPP. Organizations interested in presenting during the Teaming Connect event will be allotted three (3) minutes to pitch their capabilities, supported by one (1) slide. More information on registering for these events will be available on the MTEC website within the next several weeks.

If an Offeror is in need of additional teaming assistance, the Offeror is encouraged to reach out to the points of contact listed in Section 6.

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 https://mtec-sc.org/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 MTEC 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 MTEC to notify Offerors. All Proposers will be notified by email from MTEC 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 MTEC 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, or process, including a business process, (B) reverse engineering to address obsolescence, (C) a pilot or novel application of commercial technologies for defense purposes, (D) agile development activity, (E) the creation, design, development, or demonstration of technical or operational utility, or (F) combinations of the foregoing.

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. Any superseding KRL/TRL requirements are explicitly noted within the individual Focus Area descriptions in Section 3.3. 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: For assistance in self-assessing your technology, comprehensive definitions and reference guides for both TRLs and KRLs are available at https://mtec-sc.org/resources.

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 25-04-MultiTopic and 24-01-MPAI. 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. 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.

https://mtec-sc.org/solicitations

Focus Area 1: Policies and practices for cross-cutting prevention

Current efforts on prevention and reduction of harmful behaviors such as suicide, sexual assault, harassment, and substance misuse rely on policies, programs (curricula or other manualized sets of activities, e.g., trainings), and practices (discrete behaviors or actions). However, there is currently an over-reliance on programs, particularly trainings, for prevention. Additionally, a finding and associated recommendation of the Independent Review Commission on Suicide Prevention suggests that current training requirements (broadly speaking) exceed workload capacity, increase stress among service members, and should be reduced. Furthermore, there is limited awareness of approaches to design, select, and implement policies and practices to support prevention.

To enhance current cross-cutting preventions, the Government, specifically the National Guard, seeks the development and evaluation of non-training interventions/activities that address risk and protective factors for harmful behaviors. Priority risk/protective factors to address include: morale, fairness, work-life balance, passive leadership, toxic leadership, and workplace hostility. These non-training interventions may include **local-level policies** that can be implemented at military installations, **practices** or routine behaviors/processes executed in a military environment(s), or any programs that do not primarily rely on a training module.

The Government anticipates that proposed prototypes may involve data collection to gather current non-training approaches at military sites, literature review to gather potential options for non-training approaches, and evaluation of one or more non-training activities. Evaluation of proposed interventions should assess both outcome effectiveness and implementation feasibility, including a thorough assessment of the requirements for successful delivery (e.g., resources, infrastructure, personnel, and operational conditions) and the likelihood that these requirements can be met across varied military settings. Offerors should include a final deliverable with clear and specific guidance of the non-training approaches to enable implementation across the National Guard as well as information about the evidence behind each approach.

Focus Area 2: Fostering Service member total force fitness through integrated primary prevention

Total force fitness is a top priority for DoW leaders at the highest levels and is critical to unit readiness and mission effectiveness. There is a clear link between Service members' psychological, social, and family wellbeing and their ability to maintain physical fitness and cognitive health. National Guard and Reserve members, in particular, have high rates of obesity and face more limited access to healthcare, adequate nutrition, and physical fitness resources than their Active-duty counterparts. This suggests opportunities for current efforts to reduce rates of harmful behaviors through integrated primary prevention to facilitate physical fitness and cognitive health, improve access to nutrition education, and address inequalities in availability of nutritious food options.

The Government seeks development of interventions that account for key contributors to obesity, poor nutrition, food insecurity, cognitive wellness, and/or physical inactivity in the National Guard. Solutions should be cognizant of resource/environmental constraints, geographic limitations, and social and psychological barriers. Proposed solutions should address common risk factors for physical inactivity and/or obesity and harmful behaviors and/or adapt an existing intervention for the National Guard context. Proposed intervention should be multi-faceted, i.e., include multiple components, beyond training, such as communication approaches, informal practices, processes/procedures, communication strategy, physical health and nutrition education, and local policy changes.

The Government anticipates that proposed prototypes may involve data collection to gather current nutritional/dietary patterns of Service members, literature review to enhance known physical fitness contributors, and evaluation of current education regarding dietary patterns, access to healthier foods, and healthier food options during training.

Focus Area 3: Identify and reduce barriers to help-seeking

Help-seeking is a critical element of DoW's prevention system, and it is important to foster cultures that promote help-seeking and coordinating resource referrals. The DoW, the military Services, and local installations provide numerous resources and benefits to support Service member wellbeing and readiness. In addition, the National Guard Bureau partners with civilian organizations that extend access to resources to Service members who are not on active duty. However, research suggests that many resources are underutilized. Improving help-seeking and resource utilization requires a clear understanding of factors that influence help-seeking behavior.

The intent of this focus area is to identify and develop prototypes utilizing key drivers of help-seeking. Prototypes should prioritize high-impact resources/services and Service member populations at elevated risk for harmful behaviors. Offerors should also consider factors unique to particular contexts (e.g., very rural or geographically remote locations). After identifying key drivers, the project should develop effective approaches to increasing help-seeking, drawing from research and program evaluation conducted among both military and civilian populations. Potential approaches include but are not limited to social marketing, interpersonal communication, and policy development and implementation. Finally, the effort should culminate in the design of an intervention, tailored to military contexts (inclusive of unique National Guard drilling rhythms), that promotes help-seeking and resource utilization.

The Government anticipates that proposed prototypes may involve data collection to gather current help-seeking behaviors of Service members, literature review to enhance known drivers of help-seeking, and evaluation of current education regarding preventative and proactive measures for cross-cutting behaviors that may impact help-seeking behavior.

Focus Area 4: Prophylactic Solutions to Prevent Battlefield and Complex Traumatic Wound Infections in Austere or Contested Environments

Battlefield and complex traumatic wounds sustained in austere or contested environments are highly susceptible to infection by bacterial and fungal pathogens, including multidrug-resistant organisms. These infections can arise early after injury, complicate wound healing, increase morbidity, prolong evacuation and recovery, and reduce operational effectiveness. Prevention is the preferred countermeasure because it can reduce disease burden before infection is established, preserve force readiness, and reduce downstream treatment requirements in resource-constrained settings.

The Government seeks the development of prototypes to prevent or delay wound infections (bacterial, fungal, and/or antimicrobial-resistant) following battlefield and complex traumatic wounds, including in austere or contested environments, for use at the point of injury and in prolonged care environments (Roles 1 and 2), without negatively impacting wound healing. High-priority pathogens include *Pseudomonas aeruginosa, Klebsiella pneumoniae, Acinetobacter baumannii, Staphylococcus aureus*, and invasive fungal infections.

Specific Requirements:
This focus area of interest seeks the development of materiel solutions that have the following minimum required solution characteristics:

- Proposed prototypes should be suitable for use in operational settings where limited infrastructure, harsh conditions, and adversary actions complicate logistics, mobility, and sustainment
- 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, or a target invasive fungal infection.*
- Offerors **must** include preclinical efficacy data in the Enhanced White Paper at the time of submission

In addition, it is **strongly preferred** that proposed prototypes 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. *The Offeror shall clearly indicate if either of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

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

Out of Scope Prototypes:
This focus area is not interested in vaccines, burn wound solutions, or discovery-stage efforts. Enhanced White Papers focused on these solutions may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest.

Focus Area 5: Pathogen Agnostic Countermeasures for the Treatment of Sepsis Caused by Wound Infection

Sepsis following battlefield and complex traumatic wounds remains a significant cause of morbidity and mortality and can substantially reduce operational effectiveness. This challenge is magnified in austere or contested environments where prolonged care, delayed evacuation, and limited critical care resources may hinder timely intervention. Improved treatment solutions are needed to mitigate the downstream effects of wound infection and sepsis, preserve force readiness, and improve outcomes for Service Members injured in operational settings.

The Government seeks the development of products, including immune modulators, novel drugs, immunotherapeutics, and other pathogen-agnostic and/or host-directed prototypes, to treat sepsis following battlefield and complex traumatic wounds (excluding burn wounds), including in austere or contested environments.

Specific Requirements:
This focus area of interest seeks the development of drug and/or biological treatments for sepsis, including host-based therapeutics.

- Offerors **must** include preclinical efficacy data in the Enhanced White Paper at the time of submission

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)

The Offeror shall clearly indicate if Toxicity data is not required for the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.

Out of Scope Prototypes:
This focus area is not interested in vaccines, burn wound solutions, discovery-stage efforts, or proposals focused solely on direct treatment of wound infection rather than sepsis. Enhanced

White Papers focused on these solutions may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest.

Focus Area 6: Knowledge Product Prototypes for the Prevention of Infection in Traumatic Penetrating Wounds

Battlefield and complex traumatic penetrating wounds sustained in austere or contested environments are highly vulnerable to bacterial and fungal contamination and subsequent infection, including infection caused by multidrug-resistant organisms. Knowledge product solutions are needed to improve prevention practices, optimize clinical practice guidelines, and support decision-making in operationally relevant trauma care settings. These efforts may improve readiness, preserve operational effectiveness, and reduce downstream morbidity associated with wound infection and sepsis.

The Government seeks the development of knowledge product prototypes to optimize clinical practice guidelines for the prevention of infection in traumatic penetrating wounds.

Specific Requirements:

Proposed prototypes should optimize clinical practice guidelines for at least one of the following:

- **1** - Decipher the intricate relationship between combat polytrauma involving penetrating wounds, infections and sepsis for data-driven clinical practice guideline revisions and field medicine.
- **2** – Modernize the effectiveness of acute penetrating traumatic wound management. Proposed projects shall 1) assess the effectiveness of the Acute Traumatic Wound Management guidelines as they apply to penetrating injuries and 2) optimize these guidelines to enhance the standard of care for traumatic wound infections found in operational environments. Proposed projects are encouraged to have access to, and the ability to interpret, existing study populations and data collected from human subjects that support the goals of this Focus Area. 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 penetrating traumatic wound infections found in operational environments.
- **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 7: Bacterial Diarrhea Prevention

The Government seeks innovative prophylactic prototypes to prevent endemic and emerging infectious diseases. Proactive prevention is the most strategically desirable medical countermeasure; it eliminates the need for post-exposure treatment, offers the most cost-effective approach to disease management, and preserves force readiness by minimizing unit loss rates.

This focus area targets the development of prototypes to prevent bacterial diarrhea resulting from high-priority pathogens (*Campylobacter jejuni*, enterotoxigenic *Escherichia coli*, and *Shigella*) in operational settings.

Specific Requirements:
The Government seeks the development of a self-administered, oral intervention (not a vaccine) capable of targeting multiple high-priority bacterial pathogens (*Campylobacter jejuni*, enterotoxigenic *Escherichia coli*, and *Shigella*). Proposals may feature novel interventions, repurposed existing countermeasures, or current standard-of-care approaches evaluated for military-specific use cases.

Offerors **must** include preclinical efficacy data in the Enhanced White Paper at the time of submission (f*ailure to include this efficacy data may result in an "Unacceptable" overall proposal rating)*. Furthermore, the inclusion of toxicity data (if required by FDA) is **preferred**.

Technical approaches for this focus area may include efficacy and safety testing in validated preclinical animal models; cGMP manufacture; and safety and efficacy testing in clinical trials of prophylactics.

Out of Scope Prototypes:
This focus area will not consider proposals for vaccine-based interventions. Furthermore, solutions must exclusively target the high-priority pathogens listed above (*Campylobacter jejuni*, enterotoxigenic *Escherichia coli*, and *Shigella*); proposals targeting other pathogens will be deemed out of scope and will receive an overall "Unacceptable" rating for failing to align to a specified Focus Area of Interest.

Focus Area 8: Dengue Fever Prevention and/or Treatment Prototypes

Dengue Fever is caused by one of four related, but distinct, viruses (serotypes), which poses a threat to the globally deployed Joint Force. Recovery from infection by one serotype provides lifelong immunity against only that serotype, and later infection from another serotype can cause severe disease due to antibody-dependent enhancement (ADE), which is a scientific challenge that candidate solutions to prevent and treat Dengue Fever must address. Effective prevention and treatment of Dengue Fever is critical for future near-peer conflicts where prolonged care and preservation of operational effectiveness and reduce unit loss rate will be required and evacuations for severe disease will be greatly hindered.

Specific Requirements:
Offerors must indicate in their proposals their responsiveness to one of the following sub-focus areas:

- **Dengue Fever Prevention**: Desired prototypes include prophylactic drugs and vaccines, to prevent all four serotypes of Dengue Fever. Specific characteristics include, but are not limited to:
    - Identifying and characterizing correlates of protection for both natural infection and vaccination or determining other unknown immune markers necessary for an effective Dengue Virus vaccine.
    - Immunogenicity studies to measure type-specific antibodies in relevant animal models.
    - Evaluation of candidate vaccines to elicit a balanced type-specific immune response in relevant animal models.
    - Understand and identify ways to mitigate vaccine-induced viral enhancement risk.

- **Dengue Fever Treatment**: Desired prototypes include antibody (IgG and IgA) immunotherapeutics to treat Dengue Fever (against all four serotypes). These could be either monoclonal or polyclonal antibodies or a cocktail of antibodies, if relevant.

At the time of proposal submission for this Focus Area, it is **required** that Offerors also include the following in their Enhanced White Papers. *Offerors shall clearly indicate if any of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

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

Proposed solutions must be designed for administration via one of the following routes suitable for field or austere settings:

- Oral (PO)
- Intramuscular (IM)
- Transdermal (TD)
- Subcutaneous (SC)

Out of Scope Prototypes:
Intravenous (IV) solutions are explicitly excluded and will not be considered under this Focus Area. Enhanced White Papers focused on these solutions may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest.

Focus Area 9: Prevention and Treatment of Emerging Infectious Diseases

Emerging infectious diseases represent a significant and persistent threat to the health, mission readiness, and operational effectiveness of deployed U.S. military personnel. This modern challenge is underscored by the historical reality that diseases have often inflicted more

casualties than combat. This Focus Area seeks the development of solutions for Lassa fever virus, Crimean-Congo Hemorrhagic Fever Virus (CCHFV), and various hantaviruses, which are high-consequence pathogens that pose distinct risks to the deployed Joint Force.

Specific Requirements:
Offerors must indicate in their proposals their responsiveness to one of the following sub-focus areas:

- **Prevention of Emerging Infectious Diseases:** Develop pathogen-agnostic and/or broad-spectrum prophylactics for CCHFV and/or Lassa Fever utilizing agile platform technologies that can rapidly pivot towards future Joint Force priorities. Additional pathogens relevant to the deployed Joint Force may be included to demonstrate agility of the proposed solution.

- **Treatment of Emerging Infectious Diseases:** Develop pathogen-agnostic and/or broad-spectrum therapeutics for CCHFV, Lassa Fever, and/or hantaviruses utilizing agile platform technologies that can rapidly pivot towards future Joint Force priorities. Additional pathogens relevant to the deployed Joint Force may be included to demonstrate agility of the proposed solution. Products to treat hantaviruses that cause hemorrhagic fever with renal syndrome (HFRS) (e.g. Hantaan virus) are prioritized over those that cause hantavirus pulmonary syndrome (HPS) (e.g. Andes virus).

At the time of proposal submission for this Focus Area, it is **required** that Offerors also include the following in their Enhanced White Papers. *Offerors shall clearly indicate if any of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*:

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

Proposed solutions must be designed for administration via one of the following routes suitable for field or austere settings:

- Oral (PO)
- Intramuscular (IM)
- Transdermal (TD)
- Subcutaneous (SC)

Out of Scope Prototypes: Intravenous (IV) solutions are explicitly excluded and will not be considered under this Focus Area. Proposals focused solely on other pathogens, including endemic and emerging respiratory viruses, will not be considered and will receive an overall "Unacceptable" rating for failing to align to a specified Focus Area of Interest.

Focus Area 10: Musculoskeletal Injury Treatment

Musculoskeletal injuries are the single greatest threat to operational readiness in the armed forces. These injuries affect over 800,000 Service members annually, resulting in approximately 2.4 million medical visits and 25 million limited duty days. During training, musculoskeletal injuries account for up to 80% of the medically non-deployable force and 50% of Service members can expect to sustain at least one musculoskeletal injury each year. While deployed, combat related injuries are an ongoing threat to the Service members and there is an unmet need to accelerate the recovery from injuries that are not life-threatening and can be cared for in the pre-hospital setting. In addition, approximately 30% of all medical evacuations while deployed are due to non-battle musculoskeletal injury, with approximately 85% of those injured not returning directly to in-theater operations. Reducing this number through targeted interventions to treat musculoskeletal injuries in the pre-hospital environment has the potential to greatly impact medical readiness.

The Government is seeking prototypes for musculoskeletal injury interventions in the pre-hospital environment. To meet the intent of the funding opportunity, Enhanced White Papers submitted to this Focus Area must address ONLY one of the following sub areas:

- **Focus Area 10A: Therapeutic interventions to accelerate recovery from musculoskeletal injury:** Proposed prototypes should accelerate recovery from musculoskeletal injury and are intended to be highly applicable to pre-hospital care scenarios. The goal is to reduce the timeline of recovering from non-life-threatening injuries, to include structural (bone) or soft tissue. Animal studies are not permitted.

  Proposals for Focus Area 10A may propose either clinical translational research or clinical research.

- **Focus Area 10B: Preservation of musculoskeletal health**: Proposed prototypes should provide initial protection and preservation to facilitate later aspects of care including reconstruction and long-term rehabilitation and recovery. The focus is intended for soft-tissue injuries but may additionally apply to other applications.

  Proposals for Focus Area 10B may propose either applied research or clinical translational research.

Offerors should consider the following guidance when developing their proposals:

- Proposed prototypes should be highly relevant to the military environment or injuries sustained by the military that would not be logically addressed by other funding agencies. When appropriate (e.g. access to certain populations, stages of training, etc.), partnering with DoW collaborators or sites may be encouraged. For any proposal involving human

subjects, the proposal should demonstrate the availability of and access to a suitable patient population that will support a meaningful outcome for the study.

- Solutions must apply to the pre-hospital environment, which may be in garrison or in the operational setting.
- Offerors may propose development tasks associated with applied research, clinical translational research, and clinical research. Proposed projects for clinical research may range from small proof-of-concept trials (e.g., pilot, first-in-human) to demonstrate the feasibility or inform the design of more advanced trials, through large-scale trials to determine efficacy in relevant populations.
- Both acute trauma and overuse injuries may be included.
- Prototypes that are broadly applicable to multiple injury types are desirable, although not required.
- Injured areas may include upper extremities, lower extremities, and/or spine/torso.
- Acknowledgement of transition pathways or transition partners is highly encouraged for all proposals and required for clinical research studies.
- Offerors are encouraged to propose follow-on tasks as option periods beyond the initial scope or budget of the project.

The following Addendums are **required** to be included in addition to those listed in Section 4 of this RPP (as applicable). *The Offeror shall clearly indicate if either of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

- **Additional Data Addendum:** Offerors should include any preliminary and/or published data relevant to the proposed research.
- **Letters of Support:** Offerors must include letters of support if the proposed project involves accessing military populations or collaborators.

Out of Scope Solutions:

The following topic areas are out of scope for this focus area and will not be considered for award. Enhanced White Papers focused on these solutions may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest:

- injury prevention,
- injury diagnosis/imaging,
- human performance optimization,
- personal protective equipment,
- definitive care interventions,
- external stabilization, such as exoskeletons, braces, and splints,
- arthritis,
- neuropathy,
- spinal cord injuries,
- head and neck injuries,
- compartment syndrome,
- infection,

- ACL tears/reconstruction,
- prosthetics/orthotics,
- training protocols,
- and nutrition.

Additionally, funding from this award must **NOT** be used for:

- Basic science.
- Purely retrospective or database-related research.

Additional Information:
Awards made from this Focus Area are anticipated to begin in FY27.

For **Focus Area 10A**: **Therapeutic interventions to accelerate recovery from musculoskeletal injury**, the Government anticipates 1-2 awards of approximately $3M each with a period of performance not to exceed 36 months.

For **Focus Area 10B: Preservation of Musculoskeletal Health** focus area, the Government anticipates 2-3 awards of approximately $1.5M each for a period of performance not to exceed 36 months.

Focus Areas 11 - 14: Pain Treatment

One of the most critical challenges in Warfighter care is how to control severe pain without compromising a Warfighter's ability to fight. Pain is the single most common cause for medical evacuation from the battlefield. Current doctrine for far-forward pain management, outlined in the Joint Trauma System (JTS) Clinical Practice Guidelines (CPGs) and Tactical Combat Casualty Care (TCCC) protocols, is centered on the use of opioids (fentanyl) and ketamine. While effective, these interventions carry significant risks in a military context, including respiratory depression, cognitive impairment, and hemodynamic instability, which can be exacerbated by polytrauma and hemorrhagic shock. These side effects endanger the casualty and place additional burdens on medical personnel.

Furthermore, there is a critical need for advanced anesthetic capabilities that can support damage control resuscitation and surgery in austere settings (Role 1 and 2), where access to anesthesiologists and robust medical equipment is not guaranteed. The current reliance on specialist-dependent techniques limits the military's ability to provide life-saving surgical interventions closer to the point of injury.

To address these challenges, the Sensory Systems Program is interested in solutions for combat-relevant pain and anesthesia across the following four primary areas of interest (listed below).

As previously stated, each Enhanced White Paper **SHALL** specifically address **ONLY ONE** Focus Area of Interest. Offerors are not limited to a single Enhanced White Paper submission.

General Requirements for Focus Areas 11–14

The following guidelines apply to all submissions under Focus Areas 11, 12, 13, and 14:

All responses, regardless of the topic area addressed, should be submitted with sufficient detail to allow for a thorough evaluation of the proposed solution's scientific merit, feasibility, and relevance to the DoW. Offerors are encouraged to provide the following information, where applicable, to strengthen their submission. All proposals must clearly articulate how the proposed effort addresses a specific capability gap identified in current Joint Trauma System (JTS) Clinical Practice Guidelines (CPGs), Tactical Combat Casualty Care (TCCC) guidelines, or other formal DoW requirements documents.

Mandatory Submission Requirements (As Applicable)
As specified within each individual Focus Area (11, 12, 13, and 14), certain documentation is required for a proposal to be considered for evaluation. Offerors must refer to the specific Focus Area they are addressing to ensure all mandatory documents are included.

Strongly Encouraged Supplementary Information (All Focus Areas)
While not a mandatory requirement for all focus areas, offerors are strongly encouraged to provide the following supplementary information. These materials will assist our evaluation team in assessing the maturity, feasibility, and strategic alignment of the proposed solution. Providing this information can significantly strengthen a submission by demonstrating a comprehensive understanding of the technology development and transition lifecycle.

- **Additional Data Addendum:**
    - Comprehensive Data Sets: Any existing preliminary or supporting data sets that were not included in the main proposal. This may include exploratory toxicology, secondary pharmacology, *in vitro* assays, or full-study reports from which summary data was drawn.
    - Letters of Support from End-Users: For later-stage or device-based technologies, letters of support from military medical providers or relevant DoW laboratories (e.g., Joint Trauma System, OPMED, USAARL) are highly encouraged.
    - Biographies of Key Personnel: Brief biographies or CVs for the Principal Investigator and other key technical personnel, highlighting their relevant experience.
- **Regulatory Documentation:**
    - A draft regulatory plan or a more detailed description of the proposed FDA regulatory strategy.
    - If applicable, evidence of prior engagement with the FDA (e.g., a summary of Pre-Investigational New Drug (IND) meeting minutes).

  - A summary of the proposed quality system (e.g., cGMP, ISO 13485) that will be used during development and manufacturing.
- **Letters of support** from potential commercial partners, manufacturing organizations (CMOs/CDMOs), or clinical research organizations (CROs) that would be involved in the project.

Out of Scope Prototypes:
The primary objective of these focus areas is to identify and advance materiel prototypes for acute pain and anesthesia in military operational settings. To ensure responses are aligned with the programmatic needs of the DoW, the following research areas, technologies, and therapeutic classes are considered out of scope for these Focus Areas of Interest and will not be considered for evaluation (i.e., may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest):

- Solutions for Chronic Pain: Research focused exclusively on the treatment of pre-existing or non-trauma-related chronic pain conditions. The scope of these focus areas is limited to acute, combat-related injury. However, proposals addressing the prevention of the acute-to-chronic pain transition will be considered in scope.
- Large, Capital-Intensive, or Infrastructure-Dependent Equipment: Solutions that require large, stationary equipment, stable power grids, or clinical infrastructure not typically available at Role 1 or Role 2 medical facilities.
- Specialist-Dependent Therapies: Techniques or therapies that require administration or oversight by specialist providers (e.g., anesthesiologists, pain medicine specialists, neurologists) for routine use.
- Late-Stage Clinical Trials: Proposals for the funding of Phase II or Phase III clinical trials. This program is focused on preclinical and early-stage (Phase I) clinical development.
- New Opioid Agonists: The development of novel molecular entities that function primarily as traditional opioid receptor agonists. The program's priority is to identify opioid-sparing or non-addictive alternatives.
- Dietary Supplements and Nutraceuticals: Solutions that are not intended for development under a formal FDA regulatory pathway as a drug or medical device.
- Basic Science and Discovery Research: Foundational research that has not yet identified a lead candidate compound or a clear technological approach. Proposals must be focused on a tangible product (therapeutic, device, or knowledge product).
- Non-Materiel Solutions: Proposals focused on market research, literature reviews, policy development, or modifications to training curricula without an associated technology development component.

Focus Area 11: Operational Suitability of Existing Pain Treatments
The Government seeks the development of a knowledge product based on quantifying the impact of currently fielded battlefield analgesics (e.g., ketamine, oral transmucosal fentanyl citrate) on the operational effectiveness of a Service Member. The primary goal of this focus area is to generate definitive human performance data to inform risk/benefit decisions and create

evidence-based recommendations for the JTS to refine and optimize existing CPGs and TCCC protocols.

Prototypes for this focus area must include human-subject trials designed to measure the cognitive and physical performance of individuals following the administration of COTS/GOTS analgesics. Proposed trials should assess mission-relevant tasks (e.g., marksmanship, decision-making under stress, communication clarity, memory) in environments that simulate operational stressors like fatigue, high altitude, or temperature extremes. Proposals may investigate dosing strategies or use cases that differ from the FDA-approved label but must include a strong scientific and clinical rationale for such deviations and a clear plan to address the associated regulatory and safety considerations. The central question to be answered is: "To what extent can a Warfighter perform their duties safely and effectively after receiving this medication?"

By the end of the period of performance, prototypes are expected to provide a comprehensive data package suitable for review by military medical authorities, including:

- A Detailed Study Protocol: A complete, Institutional Review Board (IRB) and Human Research Protection Office (HRPO) / Office of Human Research Oversight (OHRO) ready protocol, including study design, primary and secondary endpoints (e.g., cognitive function, reaction time, marksmanship), and statistical analysis plan.
- Validated Human Performance Model: A final report detailing the validation of the proposed human testing model and its relevance to military operational scenarios.
- Pharmacokinetic & Pharmacodynamic (PK/PD) Data Package: Analyzed data demonstrating the absorption, distribution, and effect of the targeted analgesic(s) under the tested stress conditions compared to baseline.
- Final Technical Report & Recommendations: A comprehensive report summarizing all findings, including a "risk/benefit" analysis focused on operational performance decrements versus analgesic efficacy, and concrete, data-driven recommendations for modifying existing CPGs or TCCC guidelines.

At the time of submission, the Enhanced White Paper must include:

- A summary of previous experience conducting human performance studies, particularly those involving physiological stressors.
- A scientific justification for the proposed human performance model and its relevance to military operational tasks.

Failure to include this information/documentation may result in an “Unacceptable” overall proposal rating.

Focus Area 12: Repurposing and Novel Delivery of Approved Compounds

The Government seeks the accelerated development of safer, opioid-sparing analgesics by leveraging the FDA's 505(b)(2) regulatory pathway for repurposed drugs delivered via novel administration methods. Proposed solutions are expected to be candidate drug/device

combinations ready to enter Phase I clinical trials. Proposals must focus on the formulation of an existing FDA-approved drug into a rugged, easy-to-use delivery system (e.g., intranasal spray, sublingual film, pre-filled auto-injector) suitable for use at the point of injury.

By the end of the period of performance, proposed prototypes are expected to deliver the technical and regulatory components required to transition a repurposed compound from concept to clinical-stage development. This includes:

- Candidate Justification Report: A technical report providing the scientific rationale for the selected drug and delivery device combination, including its mechanism of action and anticipated military benefit.
- Prototype Delivery Device: A functional, lab-scale prototype of the proposed drug delivery system.
- Formulation & Stability Data Package: A comprehensive data package demonstrating the feasibility, stability, and characterization of the final drug formulation within the prototype delivery system.
- Preclinical Data Package: To strengthen the regulatory position, this package should include:
    - A Good Laboratory Practice (GLP) Pharmacokinetic/Pharmacodynamic (PK/PD) study in a relevant animal model to characterize the drug's profile with the new delivery method.
    - A preliminary, non-GLP toxicology study to demonstrate the safety of the new formulation and route of administration.
- Pre-IND Meeting Package: A complete data package and briefing document, supported by the preclinical PK/PD and toxicology data, suitable for a Pre-IND meeting with the FDA.

At the time of submission, the Enhanced White Paper must include the following. *The Offeror shall clearly indicate if either of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

- Proof-of-Concept Data: As part of the **Additional Data Addendum**, preliminary data demonstrating the feasibility of the proposed drug formulation (e.g., initial stability, dissolution, or characterization data).
- **Letter(s) of Support:** Letters from potential commercialization partners or manufacturing organizations are highly encouraged.

Focus Area 13: Development of Novel, Non-Addictive Analgesics

The Government seeks the development of a novel, non-addictive analgesic compound with a mechanism of action suitable for treating acute, combat-related trauma. Proposed prototypes are expected to include a promising lead candidate with a data package sufficient to justify further investment in IND-enabling studies.

Prototypes for this focus area are expected to include advanced preclinical assessment of new molecular entities or biologics. Proposals should utilize established, military-relevant animal

models of trauma (e.g., polytrauma, burn, penetrating injury) to demonstrate efficacy and a superior safety profile compared to morphine or ketamine.

By the end of the period of performance, proposed prototypes are expected to provide a robust preclinical data package to establish proof-of-concept and de-risk the candidate for future development. This includes:

- Efficacy Data Package: Analyzed data from military-relevant animal models demonstrating statistically significant analgesic efficacy of the lead candidate compared to standard-of-care controls.
- Safety & Toxicology Report: A report detailing the preliminary safety profile of the candidate, including data on its effects on respiratory rate, cardiovascular function (heart rate, blood pressure), and cognitive function in a relevant animal model.
- Pharmacokinetic (PK) Profile: A data set characterizing the absorption, distribution, metabolism, and excretion (ADME) of the compound in the selected animal model.
- Addiction Liability Report: A data package from a recognized animal model of abuse potential (e.g., self-administration, conditioned place preference) demonstrating a lower addiction liability compared to standard opioids.
- Lead Candidate Nomination Report: A final, comprehensive report summarizing all data and formally nominating a lead candidate for progression into IND-enabling toxicology studies, including a preliminary plan for scale-up manufacturing.

At the time of submission, the Enhanced White Paper must include the following. *Failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

  - Preliminary Data Package: Existing preclinical data, to be included in the **Additional Data Addendum,** demonstrating the compound's mechanism of action, analgesic efficacy in a relevant pain model, and any available preliminary safety/toxicology data (e.g., results of an Ames test, preliminary cardiovascular or respiratory assessments).
  - Freedom to Operate: As part of the **Letters of Support**, a statement regarding the offeror's freedom to operate or an analysis of the patent landscape for the proposed novel compound.

Focus Area 14: Advanced Anesthesia and Procedural Pain Solutions

The Government seeks the development and demonstration of a prototype system or therapeutic for the management of anesthesia and procedural pain in austere environments (Role 1 and 2). Proposed prototypes are expected to reduce the cognitive burden on providers and can be used by non-specialists.

Proposals must address one of the two following solution pathways:

- A) a closed-loop anesthetic delivery system that integrates physiological monitoring to autonomously control sedation, or

- B) a long-acting, single-administration anesthetic/analgesic suitable for providing procedural pain control without continuous infusion.

By the end of the period of performance, proposed prototypes are expected to deliver a functional prototype and a supporting data package demonstrating feasibility in a relevant simulated or preclinical environment. This includes:

- For Closed-Loop Systems:
  - Prototype System: A functional, TRL 4/5 prototype of the integrated monitoring and infusion system.
  - Algorithm & Software Package: The documented software algorithm that controls drug delivery, including the physiological parameters it responds to.
  - System Performance Report: A report detailing the performance of the prototype in a simulated or large animal model, demonstrating its ability to maintain a stable plane of anesthesia compared to manual control.
- For Long-Acting Therapeutics:
  - Formulation Data Package: Data demonstrating the successful formulation and stability of the long-acting anesthetic/analgesic.
  - Preclinical Efficacy Report: A report from a relevant animal model demonstrating the duration and depth of procedural analgesia/anesthesia from a single administration.
  - Preclinical Characterization Report: A report from a relevant animal model detailing:
    - Pharmacokinetic/Pharmacodynamic (PK/PD) analysis to confirm the duration of action and therapeutic effect.
  - A preliminary, non-GLP toxicology analysis to provide an initial assessment of the safety profile and justify progression into more formal GLP studies.

At the time of submission, the Enhanced White Paper must include the following, as applicable to the proposed prototype:

- Technical Specification Document: For device-based solutions, a document detailing the system architecture, hardware/software components, and current Technology Readiness Level (TRL) to be included in the **Additional Data Addendum.**
- Preclinical Data: For therapeutic-based solutions, any existing data, to be included in the **Additional Data Addendum,** from animal models demonstrating the duration and efficacy of the anesthetic/analgesic effect.

Failure to include the applicable information/documentation may result in an "Unacceptable" overall proposal rating.

Focus Area 15: Blast and Blunt Sensors for Exposure Monitoring

Soldiers are frequently exposed to blast and blunt impacts during training and operations, which can lead to significant brain health decrements and safety risks. Single or repetitive exposures

can link to immediate and long-term health problems such as traumatic brain injury and cognitive difficulties. To address these risks, this focus area seeks to develop and deploy technologies that monitor blast and blunt impact exposure.

The Government is seeking prototypes to address:

- A) Monitor service member brain health and/or cognitive performance.
- B) Advance human blast exposure surrogates.
- C) Develop integrated blast overpressure exposure software tools.

Proposals must address one of the two following pathways and their associated deliverables:

- **Pathway A - Advanced Blast Surrogate:**
    - A prototype of an advanced, sensor-integrated surrogate with software-enabled tunable structures that mimic human blast responses. The system must automatically report BOP exposure injury risk using both sensor and surrogate data.
- **Pathway B - TBI Incidence and Performance Tracking:**
    - A methodology and system for the precise determination of TBI incidence, alongside a neurocognitive performance assessment and tracking method designed to enhance mission readiness.

All selected performers shall deliver quarterly progress reports, a final project report, and all technical documentation required for support, verification, and validation. This includes all collected data and documentation of development efforts used to refine BOP exposure leadership requirements for tracking service member concussions and mission readiness in the training environment.

At the time of submission, the Enhanced White Paper **must** include the following, as applicable. *The Offeror shall clearly indicate if any of these requirements do not apply to the proposed project. Otherwise, failure to include this information/documentation may result in an "Unacceptable" overall proposal rating.*

- **Letters of Support:** Offerors must include letters of support if the proposed project involves accessing military populations or collaborators.
- **IRB approval documentation:** approval from an Institutional Review Board (IRB) to conduct research involving human subjects
- **Regulatory Engagement:** proof of regulatory engagement

Out of Scope Prototypes: Animal studies are considered out of scope for this focus area, will not be considered for award, and may be deemed "Unacceptable" for failing to align to a specified Focus Area of Interest.

Funding Availability, the Government currently has available a total of $10.5M for this topic. 2 awards of up to $7M are anticipated with a PoP not to exceed 48 months. These awards are expected to start in FY27.

3.4. Additional Points of Consideration

- Project Maturity: As stated in Section 3.2, this solicitation requires proposed prototypes to meet a minimum TRL/KRL of 3 unless otherwise specified. Offerors must clearly justify the asserted TRL/KRL at the time of submission, using the checklist in Addendum 1 as a reference guide.

- Industry Partners: Offerors are strongly encouraged to include industry partners to demonstrate a clear transition plan for future FDA approval and/or commercialization.

- Cost Share**:** While not a requirement, cost sharing is strongly encouraged and demonstrates partner commitment to the project.

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).
- Prototype refinement/maturation progressing towards clinical product
- Clinical feasibility studies (as needed) to support regulatory approval/clearance
- Clinical pivotal studies (as needed) to support regulatory approval/clearance
- Stability and shelf-life studies
- Prototype delivery for military-relevant testing
    - Testing of prototypes
    - System prototype demonstration in a relevant or operational environment
- Establishment of Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release
- Draft product support documentation (e.g., training guides, product inserts, etc.)
- Development of a business and/or commercialization plan for market release

- Integration of medical informatics system components and system is evaluated in a simulated environment/ Develop interfaces to supporting systems
- Advanced technical testing in a laboratory environment and ultimately in a relevant or simulated operational environment of an informatics system including actual interfaces to realistic supporting elements

3.6. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the initial PoP. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. **Examples** of potential follow-on work are **(but not limited to)**:

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

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

3.7. Restrictions on Animal and Human Subjects, Human Anatomical Substances, or Human Cadavers

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the DHA Research & Development – Medical Research and Development Command (DHA R&D – MRDC) Office of Research and Regulatory Compliance (ORRC) 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 DHA R&D – MRDC ORRC 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 DHA R&D – MRDC ORRC. Offerors shall include IRB and/or IACUC and ORRC 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 DHA R&D – MRDC ORRC 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 DHA R&D – MRDC ORRC 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 DHA. 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 ORRC 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 War Education Activity (DoWEA) Administrative Instruction 2071.3, DoWEA approval is required for research studies involving DoWEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DoWEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DoWEA 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/education/research-requests

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 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://bids.mtec-sc.org/Hub/Portal.nsf/Start?ReadForm. **The BIDS system will open for submissions no later than August 21, 2026.** Include the MTEC Solicitation Number (**MTEC-26-04-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-26-04-MultiTopic**). Note that full Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission.

All eligible Offerors may submit proposals for evaluation in accordance with the criteria set forth in this RPP. Offerors are encouraged to contact the POCs listed in Section 6 with any questions of an administrative or technical nature. All inquiries must be submitted prior to the final Enhanced White Paper submission deadline.

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**. MTEC will not 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*): 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 to 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.* **Offerors must carefully review their specific Focus Area of Interest in Section 3.3 to determine if this documentation is a mandatory requirement or encouraged for their submission.**

Focus Area Specific Submission Documents: In addition to the submission documents described above, several focus areas require additional documents. Offerors must carefully review their specific Focus Area of Interest in Section 3.3 to determine if these documents are a mandatory requirement or encouraged for their submission. 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.

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 Focus Area Specific Submission Documents (i.e., Letters of Support, Biographical Sketches, 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, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission may be requested after completion of the technical evaluation to include (but not limited to) the following:

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

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

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

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

Required Submission Documents (2): Submit to contracts@mtec-sc.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 may 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 must provide a detailed breakdown of all projected direct and indirect costs. As applicable, direct costs should include elements such as direct labor, materials, equipment, and Other Direct Costs (ODCs). Indirect costs typically include fringe benefits, Facilities & Administrative (F&A) rates, and General & Administrative (G&A) expenses. Offerors must provide a detailed justification for all proposed material and ODC costs. For additional guidance on cost proposal preparation, refer to the MTEC PPG.

Those Offerors invited to submit a Cost Proposal are encouraged to contact MTEC 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 2.9 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

5.1 Preliminary Screening

MTEC 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 MTEC. Additionally, the Government reserves the right to request additional information or eliminate Enhanced White Papers that do not meet these requirements from further consideration.

5.2 Enhanced White Paper Evaluation

MTEC will distribute all Enhanced White Papers that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source

selection and determine which Offerors will be invited to submit a Stage 2 cost proposal based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Enhanced White Papers against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all Enhanced White Papers will be evaluated based on the following factors.

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

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

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

- Hypothesis and objectives;
- Scientific rationale with supporting preliminary data;
- Experimental design, feasibility, and risks;
- Ability for the technical and management team to execute the proposed SOW in an efficient and effective manner (to include addressing DHA R&D – MRDC's Office of Research and Regulatory Compliance 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 to engage in a dialogue with the Government. Upon completion of the Stage 1 evaluations, Offerors may be selected for funding (receive an overall recommendation of "Award"), placed into the basket, or not selected. Selection of prototype projects is a highly competitive process and is based on the evaluation of the Enhanced White Paper's technical merit, programmatic considerations, and the availability of funds. Therefore, Enhanced White Papers that receive the highest merit ratings and thus demonstrating technical merit are not automatically recommended for funding as such decisions consider funding priorities and how to best achieve program objectives. All Offerors will receive feedback to include a summary of the technical evaluation for their proposal submission. Additionally, Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 4.3 for additional instructions and Addendum 5 for details regarding the anticipated Stage 2 evaluation. Offerors are advised that, due to the anticipated high number of Enhanced White Paper submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback.

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

Definition of General Terms Used in Evaluations:

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

6 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Technical and membership questions should be directed to the MTEC Senior Technical Program Manager, Chuck Hutti, Ph.D., chuck.hutti@mtec-sc.org
- All other questions should be directed to the MTEC Program Manager, Daniel Vala, Daniel.vala@mtec-sc.org

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
API	Application Programming Interface
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
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
DoW	Department of War
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
OHRO	Office of Human Research Oversight
ORRC	Office of Research and Regulatory Compliance
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.

Dates of submission and signature of official authorized to obligate the institution contractually.

[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 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 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 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 - Policies and practices for cross-cutting prevention**.

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.
- 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. See section 3.2 for additional information.

  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 section 3.2 for further information regarding expected scope of work for advancement toward the next TRL.
- Describe relevant non-clinical data and/or clinical preliminary data.
- Describe your demonstration of the manufacturing feasibility of the prototype.

Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.
- If you are proposing clinical research and/or trials, then please briefly describe your technical approach here in the Enhanced White Paper but include full details in Addendum 2 – Extramural Research Involving Human Subjects.

Anticipated Outcomes/Impact

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

Potential Follow-On Work

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

Technical and Management Team

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

Resources

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

Market and Business Model

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

Product Development Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).

- Describe previous interactions with the FDA related to this proposed prototype solution (e.g., pre-submission meeting) but include full details in Appendix 6 – Documentation of FDA Engagement.
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.
- If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.

Schedule

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

Risk Identification and Mitigation

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

Rough Order Magnitude (ROM) Pricing

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

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

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.

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. Comprehensive definitions and reference guides for both TRLs and KRLs are available at https://mtec-sc.org/resources. 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 26-04-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

MTEC will evaluate the cost proposed together with all supporting information for realism (as applicable, dependent upon contract type, i.e., Firm Fixed Price, Cost Reimbursable), reasonableness, and completeness as outlined below. MTEC will then 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.

MTEC 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**. MTEC 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. MTEC will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. MTEC 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 MTEC'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 into negotiations with most Offerors recommended for funding with MTEC 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**.

R= Required | E = Encouraged | RA = Required if applicable to the proposed solutions

Focus Area	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Enhanced White Paper	R	R	R	R	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	R	R	R	R
Statement of Work / Milestone Payment Schedule	R	R	R	R	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	R	R	R	R
Intellectual Property and Data Rights Assertions	R	R	R	R	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	R	R	R	R
Extramural Research Involving Human Subjects	RA	RA	RA	RA	RA	RA	RA	RA	RA	R	R	RA	RA	RA	R
Documentation of FDA Engagement	RA	RA	RA	R	RA	RA	R	R	R	RA	RA	R	RA	RA	R
Letters of Support	E	E	E	E	E	E	E	E	E	R	E	E	R	E	R
Biographical Sketches	E	E	E	E	E	E	E	E	E	E	E	E	E	E	E
Additional Data Addendum	R	R	R	R	R	R	R	R	R	R	E	R	R	RA	E