Request for Project Proposals

Solicitation Number: MTEC-22-08-BDA

"Burn Digital Assessment"

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: June 14, 2022

White Paper Due Date: July 14, 2022
Noon Eastern Time

Table of Contents

1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) engage in biomedical research and prototyping;

(b) exploration of private sector technology opportunities;

(c) technology transfer; and

(d) deployment of intellectual property (IP) and follow-on production.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, "nontraditional" defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at https://mtec-sc.org/.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the DoD OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the U.S. Army Medical Materiel Development Activity (USAMMDA). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b (now 4022). Strategic oversight for the award(s) supported by this RPP will be provided by the Warfighter Expeditionary Medicine and Treatment (W-EMT) Project Management Office (PMO).

This RPP is focused on a burn digital assessment capability that will be utilized at the Battalion Aid Station (BAS), Brigade Support Aid Station, Forward Resuscitation and Surgical Detachment (FRSD), and field hospital (FH) to inform triaging, evacuation, and resourcing decisions, contributing to reduced surgical burden and increased Soldier return to duty.

2 Administrative Overview

2.1. Acquisition Approach

This RPP will be conducted using a White Paper approach. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for MTEC members. Based on the Government's evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 and will be required to submit a full proposal for more detailed evaluation.

The due date for White Papers is found on the cover page of this RPP. White Papers may not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

- **Stage 1:** White Papers submitted under this RPP shall follow the MTEC White Paper Template provided in Section 8.

- **Stage 2:** Offerors whose solutions are selected for further consideration based on White Paper evaluation will be invited to submit a Full Proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements.

Note that the terms "White Paper" and "Proposal" are used interchangeably throughout this RPP. Offerors are hereby notified that the Government intends to utilize a **rolling downselect** approach **during the performance of prototype projects** awarded as a result of this RPP. Using this approach, the Government intends to award prototype projects, structured into two Periods of Performance (PoPs), with an initial base period (PoP1) (see PoP and funding details under Section 2.2 below) reflecting the first of the two PoPs. After an In-Process Review (IPR), an evaluation of project deliverables and other considerations to include progress towards completion of the base PoP1 tasks, the Government intends to award a second PoP, referred to as the subsequent PoP (PoP2), to the performer(s) that demonstrates a best value approach for follow-on tasks. Award decisions for the subsequent PoP2 work will be made during the Go/No-go Decision Point which is expected to occur prior to the end of the base PoP1 (tentatively projected at t = 20 months). See the proposal format requirements and instructions to Offerors detailed under Section 3 ("Technical Requirements") of this RPP for additional details.

The Government reserves the right to end all awarded projects after the initial base period and award no subsequent PoP2 tasks depending on project outcomes, availability of funding, and changing Government requirements. Additionally, the Government reserves the right to

negotiate with performers (selected for award under this RPP), on a noncompetitive basis, to award additional tasks onto successful projects for the further development of the product solution. While this is anticipated to occur after the subsequent PoP2 , this may occur at any time following award of OTA for prototype projects.

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 2371b (now 4022) section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award (RPA) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website 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 White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement*.** If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has available a total of approximately **$4.8 million (M)** for this effort. Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program.

It is expected that MTEC will make **multiple awards** to qualified Offerors in Fiscal Year (FY) 2023 to accomplish the scope of work. If a single proposal is unable to sufficiently address the entire scope of the RPP, several Offerors may be asked to work together in a collaborative manner.

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

The base PoP1 is **not anticipated to exceed 24 months**.

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.6 for additional details. As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program.

2.3. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the technical requirements outlined in Section 3. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.4. Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. **In accordance with the Proposal Preparation Guide (PPG), please mark all Confidential or Proprietary information as such.** An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain proposals within their program areas, allowing for opportunities to attract supplemental funding sources. Therefore, on your White Paper Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your proposal for the purposes of engaging in outreach activities with these private entities. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, all Technical Evaluation Panel participants, which may include contractor support personnel serving as nongovernmental advisors, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

2.5. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. The following two resources may help Offerors provide a more complete team for this requested scope of work.

2.5.1. MTEC M-Corps

The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning,

cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction Advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls (CMC), clinical trials, concepts and requirements development, design development and verification, manufacturing, process validation, manufacturing transfer quality management, regulatory affairs]. Please visit https://www.mtec-sc.org/m-corps/ for details on current partners of the M-Corps.

2.5.2. MTEC Database Collaboration Tool

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

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

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

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

2.6. Offeror Eligibility

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

2.7. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP.* If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution (see **Section 7.4 of the PPG** for definitions); provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and

the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

2.8. Cost Sharing Requirements

In order to be compliant with 10 U.S.C. §2371b (now 4022), Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG**. Beyond that, cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see **Section 7.4 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award.

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).

2.9. MTEC Assessment Fee

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

2.10. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant Research Project Award. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding IP and Data Rights. **It is anticipated that anything created under this proposed effort would be delivered to the Government with Government Purpose Rights or Unlimited Data Rights unless otherwise asserted in the proposal and agreed to by the Government**. Rights in technical data shall be determined in accordance with the provisions of the MTEC Base Agreement.

Note that as part of Stage 2 of the RPP process (submission of a full proposal), 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.

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

2.11. Expected Award Date

Offerors should plan on the period of performance beginning January 31, 2023 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.12. Anticipated White Paper Selection Notification

As the basis of selections is completed, the Government will forward their selections to the MTEC CM to notify Offerors. All Offerors will be notified by email from the MTEC CM of the results of the evaluation. Those with favorably evaluated white papers will move forward to the next phase of the process, while those not selected will receive evaluation rationale for non-selection.

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

3 Technical Requirements

3.1. Background

It is anticipated that, in future conflicts, the Army will have to fight and win across multiple domains in contested locations where air, ground, and nautical evacuations of casualties will be extremely challenging. Additionally, the explosive weapons that will likely be used against U.S. forces will be more powerful than what has been used to date, resulting in higher numbers of casualties with significant burn injuries including larger, more severe burns.

Evacuating casualties within theater could take days or weeks due to contested air space and other area denial maneuvers by the enemy. As such, medical providers will have to manage burn casualties for longer periods of time at earlier roles of care. This will require that those providers decide how best to resuscitate those casualties and whom to prioritize for evacuation. With only minimal burn wound management tools available in the pre-hospital environment, determining resuscitation needs and evacuation priority can significantly impact return to duty rates and survivability. However, extant burn management tools do not include an objective burn assessment tool.

Providers currently assess burns using estimation methods such as the Rule of Nines or the Rule of Palm. The Rule of Nines breaks the body down into 9% increments (e.g., front of leg = 9%, back of leg = 9%, entire arm = 9%) to help medical providers make a quick estimate of the total body surface area (TBSA) burned. Similarly, the Rule of Palm states that the size of a person's palm (not including fingers and thumb) is equivalent to approximately 1% of their TBSA. While this provides an approximate (albeit unreliable) measure of TBSA, it does not assist with discerning burn depth. This is a difficult task even for experienced burn surgeons because of the varying ways burn wounds can appear visually. Burn surgeons average only a 60% accuracy when discerning full-thickness burns from partial-thickness burns. This is because more serious, full-thickness burns can appear less severe than a less serious, partial-thickness burn.

Because the degree of burn severity encompasses both TBSA and burn depth, it is extremely challenging for far-forward medical providers (with less training and experience than burn surgeons) to accurately assess burn severity. Therefore, a digital assessment device will enable providers an objective measure of burn severity, enabling them to more accurately resuscitate and later triage and prioritize burn casualties. This enables more severe (but savable) burn casualties to be prioritized for evacuation, while preventing unnecessary evacuation for less severe burn casualties who could be treated closer to (or at) their unit.

The Government is seeking a burn digital assessment capability that will be utilized at the Battalion Aid Station (BAS), Brigade Support Aid Station, Forward Resuscitation and Surgical Detachment (FRSD), and field hospital (FH) to inform triaging, evacuation, and resourcing decisions, contributing to reduced surgical burden and increased Soldier return to duty. Technological advances that contribute to a product solution that meet these requirements will be considered as possible candidates for fielding by the Burn Treatment and Skin Repair acquisition program.

3.2. Solution Requirements

The overall goal of this RPP is to develop a hand-held, rugged device capable of providing an objective measure of burn severity by calculating burn size (in terms of TBSA) and burn depth (e.g., partial-thickness, full-thickness), including the proportion of TBSA for the various burn depths. The minimum acceptable technology readiness level (TRL) at the time of submission of the White Paper is at least TRL 5. The definition of TRL 5 is summarized below [full definitions of all TRLs – https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf]:

- TRL 5 Decision Criterion for *Medical Devices* – Investigational Device Exemption (IDE) review by the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health results in determination that the investigation may begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.
- TRL 5 Decision Criterion for *Pharmaceuticals* - A decision point is reached at which it is determined that sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an Investigational New Drug (IND) application.
- TRL 5 Decision Criterion for *Biologics* - A decision point is reached at which it is determined that sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.

Required characteristics of the ideal solution [Note: Proposed prototypes do not have to meet all of these specifications at the time of white paper submission, but Offerors must describe what they do plan to accomplish in PoP1 and how they plan to satisfy all of the solution requirements in subsequent PoPs.]:

- FDA clearance for assessing burn size and depth
- Provides reliable, objective measure of burn size in terms of TBSA

- Provides an objective measure of the proportion of TBSA for various burn depths (e.g., partial-thickness vs. full-thickness)

- Non-invasive device that does not cause pain (e.g., non-contact)

- Simple to use such that a physician's assistant or medic could make the assessment

- Provides simple output within minutes that does not require further interpretation.

- Appropriate for use at Role of Care (ROC) 1 (unit-level medical care, i.e., Battalion Aid Station) [Refer to Chapter II of Joint Publication 4-02 "Joint Health Services" for ROCs definitions: https://www.jcs.mil/Portals/36/Documents/Doctrine/pubs/jp4_02ch1.pdf
    - Purpose of Role 1:
        - Provides primary healthcare, specialized first aid, triage, resuscitation, and stabilization
        - Casualty collection
    - Providers:
        - Treatment provided by medics
        - Expanded medical treatment provided by physician assistant, physician (if available), independent duty corpsman/medical technician, pararescueman
    - Role 1 facilities include:
        - Tent
        - Limited power
        - Limited space
        - Highly mobile
        - Not substantially climate controlled, if at all

- Hand-held, self-contained device with size, weight, and cube that enables use at ROC1

    - The system shall be no greater than 12 x 8 x .5 inches

    - The system shall weigh between 1 to 6 pounds

    - Display: The system shall have a 5" – 13" display that is sunlight readable LCD (or similar) display with 720p anti-reflection and anti-glare technology and glove-touch capable. A minimum brightness of 800 up to 1400 nits for optimal field usability and readability in direct sunlight.

    - The system shall operate off of 100-240 VAC 50/60 Hz and 12-24 VDC powers sources. Power sources shall be capable of charging internal batteries while the system is running.

  - Hot-swappable, rechargeable batteries
  - Meet MIL-STD-810 standards for vibration, temperature, humidity, altitude, and shock, as well as Ingress Protection rating IP65 dust and water compliant
  - Designed to be maintained at the lowest level possible as appropriate for the system (e.g., field level, depot level, contractor logistics support). It is understood that this will need to be worked out iteratively as the prototype matures

- Compatible with other burn and lifesaving treatments
- Has minimal training requirements
- Compliant with DoD Cybersecurity requirements
  - DoDI 8510.01 Risk Management Framework (RMF)
  - DoDI 8500.01 Cybersecurity
  - Complete the requirements under the RMF and obtain an Authority to Operate (ATO) and or Assess Only. This will facilitate software updates, diagnostics, and other sustainment tasks that require computer resources
- Prototype must eventually become a commercially viable product or technology that will be brought to market. (NOTE: It can be marketed for the same or a different indication in the civilian market than what the DoD is seeking. If a different indication will be sought for the civilian market, FDA approval for the military's intended use/indication will still need to be secured.)

3.3. Additional Preferred Characteristics

Beyond the required characteristics outlined in Section 3.2, Offerors may consider addressing the following characteristics which are **preferred, but not required**. Proposed solutions that address the required characteristics described in Section 3.2 and additional preferred characteristics outlined here may be preferred by the Government evaluators and military end-users. Therefore, Offerors are encouraged to describe how their proposed prototype may meet none, some, or all of the following additional preferred characteristics:

- In cases of very large or circumferential burns, device can aggregate multiple readings from a single casualty into a total reading (i.e., total measure of burn size)
- Maps mixed-depth burns such that regions of full-thickness burns can be identified

- Can be used in a variety of light conditions

- Is multipurpose and can be used to assess other types of combat injuries (e.g., perfusion, amputation, critical wound ischemia)

3.4. Additional Points of Consideration

- Project Maturity: This solicitation is not meant to support development of a new prototype but should focus on fine tuning and optimization of existing prototypes or other technologies.

- Industry Partners: MTEC considers that a white paper involving an industry partner (or alternative organizations) to serve as the regulatory sponsor and commercialization partner may have the greatest level of success, especially considering that the eventual goal is to obtain FDA clearance/approval.

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

- Military Impact: Offerors must demonstrate an understanding of the military need for a burn digital assessment device.

- Technical Characteristics: An ideal solution would meet the characteristics described above. Although White Papers that propose to meet all of the solution characteristics outlined above are preferred, we encourage you to submit even if you cannot currently meet all these specifications within the project period of performance. The Government may consider lesser responses based upon the specifications that could be met and the team's approach to meeting the other requirements over time. However, it is expected that an Offeror's White Paper will describe in detail what they plan to accomplish and how they plan to satisfy all of the solution requirements either during the performance of the resultant award or beyond that period (Offerors should specify the projected timeline).

- Training Requirements: Offerors must describe the anticipated training requirements for their prototype to be used by end users described above, e.g., medics and other non-licensed medical personnel and potentially non-medical responders, if appropriate.

3.5. Go/No-go Decision Point for Downselect

Prior to the end of the initial PoP (PoP1), which is tentatively projected to occur at 20 months into PoP1, the Government will conduct an in-process review (IPR), in which the Awardees will attend and participate in, to assess the work completed for each PoP1 performer. The IPR will be an in-person meeting at USAMRDC at Fort Detrick, MD; associated travel costs should be included in the Rough of Magnitude (ROM) for Stage 1. Following the IPR, the Government intends to

down-select Awardees to a smaller number for continuation of funding for the conduct of follow-on work in a subsequent PoP (PoP2) of the prototype project. This down-select represents the Go/No-go Decision point between PoP1 (initial) and PoP2 (subsequent). Subsequent Go/No-go decisions may also be implemented.

In preparation for the IPR, each Awardee shall submit full details of the tasks proposed for the subsequent PoP (PoP2) phase, in separate technical and cost volumes, as a deliverable to the Government. The exact due date for this deliverable is TBD (anticipated on or about 2 weeks prior to the date of the IPR). This deliverable will be reviewed and evaluated as part of the Go/No-go decision point during which time the Government will make award recommendations for the subsequent PoP selections.

All Offerors responding to this RPP **shall account for the IPR requirement and associated deliverable requirement** by identifying these as a milestone(s) in the Stage 1 (White Paper) proposal submission (under the "Anticipated Outcomes" section of the white Paper and elsewhere, as appropriate).

3.6. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. The Government may consider funding any of the following (but not necessarily limited to the) work listed below during any period (i.e., PoP1, PoP2) of the awarded prototype project(s) to include any non-competitive follow-on work (which may proceed PoP2 tasks):

- Prototype refinement/maturation progressing towards clinical product
- Pre-clinical work (as needed) to support an IDE (or other appropriate FDA) submission
- Animal studies under Good Laboratory Practice (as needed) to support IDE (or other appropriate FDA) submission
- IDE (or other appropriate FDA) submission
- 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 at US Army Institute of Surgical Research
- Testing of prototypes at Army Medical Department
- Product demonstrations
- Establishment of Good Manufacturing Practice manufacturing for clinical trials and for market release
- Initial production runs; first article testing, etc.
- Low rate initial product runs to reach Full Operating Capability

- Draft product support documentation (e.g., training guides, product inserts, etc.)

3.7. Restrictions on Animal and Human Subjects

White Papers and proposals must comply with 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 Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the USAMRDC Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), HRPO, prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP ACURO, in addition to the local IACUC of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

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

3.8. Guidance Related to DoD-Affiliated Personnel for Participation

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

4 White Paper Preparation

4.1. General Instructions

White Papers should be submitted by the date and time specified on the cover page using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission.

The White Paper format (Section 8 of this RPP) provided in this MTEC RPP is mandatory and shall reference this RPP number (**MTEC-22-08-BDA**). Note that Cost Proposals are only required for Stage 2 and are not part of the initial White Paper submission. However, Offerors are required to submit a Rough Order of Magnitude (ROM) pricing in accordance with the White Paper template (Section 8 of this RPP). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the White Paper submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit White Papers for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DOD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Stage 1 White Paper

Offerors submitting White Papers in response to this RPP shall prepare all documents in accordance with the following instructions:

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable, searchable, and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames shall not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline**. Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

Required Submission Documents (1): Submitted via BIDS

- **White Paper:** one PDF document (5MB of lower)
- **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**Attachment 6 of the PPG**)
- **Technology/Knowledge Readiness Level Checklist:** one Word or PDF document (**Addendum 1 of this RPP**)

Page Limitation: Each White Paper is limited to four (4) pages plus a cover page (5 pages total). The White Paper must be in 11-point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font 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 1 inch. The MTEC staff will share white papers with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.*** White Papers exceeding the page limits specified above may not be accepted.

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

Offerors that are recommended for Stage 2 will receive notification letters which will serve as the formal request for a Full Proposal. These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that MTEC members who are invited to participate in Stage 2 will be required to submit the following information:

Required Submission Documents (8): Submit via BIDS (5MB or lower)

- **Technical Proposal:** one word or PDF document (see **Section 6.2 of the PPG** for more information)
- **Section I: Cost Proposal Narrative:** one Word or PDF document (see **Section 7.2 of the PPG** for more information)
- **Section II: Cost Proposal Formats:** one Excel or PDF document (see **Section 7.3 of the PPG** for more information)
- **Warranties and Representations:** one Word or PDF document (**Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**Attachment 4 of the PPG**)
- **Current and Pending Support:** as one Word or PDF document (**Attachment 5 of the PPG**)
- **Technical Addendum for the Subsequent PoP Work (PoP2)** (**Addendum 2 of this RPP**)

The following information provides additional information related to each of the required documents for the full proposal submission. The Technical Proposal and Cost Proposal must be submitted in two separate volumes and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following. **Each document will be uploaded to BIDS separately (see Attachment 7 of PPG for BIDS instructions).**

- **Technical Proposal (information provided in Section 6 of the PPG)**
  The Technical Proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (**MTEC-22-08-BDA**). Refer to section 6.2 of the PPG for instruction regarding the preparation of the Technical Proposal (also referred to as Volume 1).

- **Cost Proposal (information provided in Section 7 of the PPG)**
  The Cost Proposal should clearly delineate your costs. Each cost proposal should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable. The Cost Proposal shall be submitted in two separate sections: the Cost Proposal Narrative (**Section 7.2 of the PPG**) and, separately, Cost Proposal Formats (**Section 7.3 of the PPG**). Offerors are encouraged to use their own cost formats such that the necessary

detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG are **NOT** mandatory.

- **Warranties and Representations (template provided in Attachment 3 of the PPG)**
  One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required for each proposal.

- **Statement of Work (template provided in Attachment 4 of the PPG)**
  One Word (.docx or .doc) or PDF file. Provide a Statement of Work as a separate document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects proposal for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below. The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule (MPS). Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

- **Current and Pending Support (template provided in Attachment 5 of the PPG)**
  One Word (.docx or .doc) or PDF file. The Offeror shall provide this information for all key personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and non-government), including the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), role, brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap. If there is no current and/or pending support, enter "None."

- **Technical Addendum for the Subsequent PoP Work (PoP2) (see Addendum 2 of this RPP)**
  One Word (.docx or .doc) or PDF file. The PoP2 work will be dependent on the advancement in prototype maturity of the prototype at the end of the base PoP1 of up to 24 months, as it applies to each resultant award(s). This addendum is intended to provide the Sponsor with information on the Offeror's plan for work beyond the base PoP1.

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4. White Paper and Proposal Preparation Costs

The cost of preparing White Papers (and, potentially, a Full Proposal) in response to this RPP is not considered a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not considered a direct charge to any resulting award or any other contract.

4.5. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the PPG.

4.6. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation, as required by the provision, to the CM. For more information, please refer to Section 6.1.2 of the PPG.

5 Selection

5.1. Preliminary Screening

The CM will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. Additionally, the Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Section 3 of the PPG). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (detailed within Section 3 of the PPG) will be determined based upon the ratings shown in Table 1:

TABLE 1 - COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	**DESCRIPTION**
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2. White Paper (Stage 1) Evaluation

The CM will distribute all White Papers that pass the preliminary screening (described above and in Table 1) to the Government for full evaluation. Evaluation of White Papers will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each White Paper against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The 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 White Paper as outlined in Section 2.5. The Government will evaluate White Papers submitted under this RPP using the following criteria listed in descending order of importance:

Evaluation Factors (Stage 1 – White Paper)

1. **Technical Approach**
2. **Project Management**
3. **Cost Reasonableness**

Evaluation Factor 1 – Technical Approach:

Reviewers will assess the technical approach based on:

- How well the white paper defines and describes a prototype that can already meet or be modified to meet the required characteristics as identified in Section 3.2 and any additional preferred characteristics as set forth in Section 3.3 of this RPP, including:
    - How the prototype works, how it is used, and by whom.
    - Preliminary data, sound scientific rationale, and demonstrated proof-of-concept that supports the prototype's current or proposed ability to meet the requirements.
    - Any work done to date to support regulatory clearance / approval of the prototype to include expected regulatory strategy / plan and any interactions with FDA (submissions, communications and meetings).
    - Any work done to date to support achievement of an ATO under the RMF review processes.
- How well the white paper proposes work and a methodology that supports achieving the technical objectives and further development of the prototype to meet the requirements.
- The appropriateness of the intended commercialization strategy for the prototype.
- How well the proposal identified intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.

Evaluation Factor 2 – Project Management:

The soundness of the proposed schedule that shows that the project can be completed within the proposed timeline, and whether the background and expertise of the personnel are appropriate to accomplish the proposed development, test, evaluation, approval / clearance and commercialization.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach and Project Management evaluation factors. Please also refer to Section 5.5 for definitions of general terms used in technical evaluations.

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.

Evaluation Factor 3 – Cost Reasonableness:
Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. Cost Reasonableness will be based on Table 3 below (Cost Reasonableness Evaluation Factor Ratings Definitions).

TABLE 3 - "COST REASONABLENESS" EVALUATION FACTOR RATINGS DEFINITIONS	
RATING	**DESCRIPTION**
SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project.
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Upon review and evaluation of the White Papers, Offerors who are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were

not favorably evaluated will be provided feedback on the evaluation. Note that Offerors should receive an overall rating of at least "Acceptable" or higher in order to be considered for Stage 2; however, the Government reserves the right to make final evaluation decisions based upon programmatic relevancy and overall best value solutions determined to be in the Government's best interest.

5.3. Full Proposal (Stage 2) Evaluation (Only for Offerors Recommended for Stage 2)

The CM will conduct a preliminary screening of received proposals to ensure compliance with the Stage 2 RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. Stage 2 submissions that pass the preliminary compliance screening will be evaluated by the Government technical evaluation panel who will make recommendations to a Source Selection Authority.

Evaluation will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Ratings Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The CM will evaluate the cost proposals for those Offerors recommended for award, as detailed below, for realism, reasonableness, and completeness.

Evaluation Factors (Stage 2 – Full Proposal)

1. **Technical Approach**
2. **Potential for Transition and Commercialization**
3. **Cost/Price**

Evaluation Factor 1 – Technical Approach:

The Offeror's proposal will be assessed for:

- The likelihood of successfully achieving the requirements of the technology as defined above in order to meet the government's needs. The likelihood of success will be determined by considering the soundness and clarity of the scientific rationale and technical approach, including technical merit of proposed research experiments and product development efforts. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan.
- The SOW should provide a succinct approach for achieving the project's objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed work and as needed, meet ACURO, HRPO, and FDA regulations.
- The proposed effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable(s) advance the TRL.

- Military relevance is a critical component of proposal submission. This relevance includes the health care needs of military Service members, enhanced capabilities of their care providers, training requirements, and the austere environment in which treatment is performed.
- A description of the project team's experience, key personnel, and corporate experience should demonstrate an ability to execute the SOW. Any relevant experience achieving FDA clearance / approval and commercializing medical products should also be included.
- The proposal will also be evaluated on the soundness of the proposed scope of work for a Subsequent Period of Performance and how that work builds upon the proposed work under the Base Period of Performance and furthers the prototype's maturity towards regulatory clearance, commercialization, and military relevance.

Evaluation Factor 2 – Potential for Transition and Commercialization:
The Offeror's proposal will be assessed for:

- How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of development and clinical testing.
- How well the project will translate from promising, well-founded basic or clinical research findings into clinical applications for military Service members.
- How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- How well the regulatory strategy is described and how well the Offeror provides sufficient evidence of their progression through their identified regulatory pathway as well as how the proposed work advances their prototype towards regulatory clearance / approval for the intended use by the military.
- How well the cybersecurity regulatory compliance strategy is described (i.e. steps to be taken/already taken towards achieving ATO for a medical device on a DoD network).
- How well the manufacturing and commercialization strategies are described, including current or potential use of contract manufacturing organizations, intended quality management systems, sales and distribution channels, etc.

Evaluation Factor 3 – Cost/Price Evaluation:
In addition to the evaluation factors listed above, the MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete. Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) **Realism**. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's technical approach and Statement of Work.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) **Reasonableness**. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must, in its nature and amount, represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

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

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

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

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

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking

information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

Government Access to Information

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

Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings contained within this RPP. The overall award decision will be based upon a Best Value determination and the final award selection(s) will be made to the most advantageous offer(s). Based on the results of the Stage 2 Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the proposal to include the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4. Award Recommendation

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. Select the proposal (or some portion of the proposal) for award
2. Place the proposal in the Basket if funding currently is unavailable; or
3. Reject the proposal (will not be placed in the Basket)

5.5. Definition of General Terms Used in Evaluations

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

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

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

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

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

6 Points-of-Contact

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

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Director of Research Programs, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ACURO	Animal Care and Use and Review Office
ATI	Advanced Technology International
BAS	Battalion Aid Station
CM	Consortium Manager
CMA	Consortium Member Agreement
DoD	Department of Defense
DODI	Department of Defense Instruction
EC	Ethics Committee
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FH	Field Hospital
FOIA	Freedom of Information Act
FRSD	Forward Resuscitation and Surgical Detachment
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPR	In-Process Review
IRB	Institutional Review Board
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium

NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
ORP	Office of Research Protections
PDF	Portable Document Format
PMO	Project Management Office
POC	Point-of-Contact
PoP	Period of performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RMF	Risk Management Framework
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TBSA	Total Body Surface Area
TRL	Technology Readiness Level
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
W-EMT	Warfighter Expeditionary Medicine and Treatment

8 White Paper Template

Cover Page (1 page)

[Title of White Paper]

[Principal Investigator]

[Institution]
Address: [Address of Offeror]
Phone Number: [Phone Number of Offeror]
Email Address: [Email Address of Offeror]
DUNS #: [DUNS #]
CAGE Code: [CAGE code]

Statement that "This White Paper is submitted pursuant to the MTEC-22-08-BDA RPP."

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

Nontraditional Defense Contractor or Nonprofit Research Institution %: (*see Section 3 of the PPG for more information*)

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO
[As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

White Paper (4 pages)
(*5 pages total including the cover page*)

Title: [Insert descriptive title of project]

Principal Investigator: [Insert name, organization, email address, phone number]

Background: [Briefly state the problem that the White Paper is addressing.]

Approach: [Briefly describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Include the current status of your approach Indicate the technology or knowledge readiness level (TRL) at the time of submission and at end of the proposed PoP. Full definitions of TRLs can be found here. . Note: References are included within the page limit. There is no required format for the inclusion of references.]

Objectives: [Specify the objectives of the proposed effort for the base PoP1 of up to 24 months.]

Technical Strategy: [Outline the proposed methodology for the base PoP1 of up to 24 months **by task** in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.].

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work. Also provide a high-level summary of potential follow-on tasks beyond the initial PoP, if applicable.]

Training Requirements and How-to-Use Description: [Briefly describe the anticipated training requirements for the proposed prototype to be used by end users (e.g., medics and other non-licensed medical personnel and potentially non-medical responders), if appropriate. In addition, describe how the ROC1 military personnel would actually use the solution in the far forward environment. The intent is for Offerors to provide insight into the proposed solution's ease of use at ROC 1.]If invited to Stage 2 of the RPP process, Offerors will have an opportunity to elaborate on this section as necessary.]

Potential for Follow-On Work: [Additional funding in PoP2 may be available for potential follow-on work related to the proposed prototype. This section is intended to provide the Sponsor with information on the Offeror's plan for potential follow-on work beyond the base PoP1.]

Technical Maturity and Transition or Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed solution, anticipated regulatory pathway (if applicable) and transition or commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

Schedule: [Provide an overview of the timing of initiation, duration, and completion of project activities over the course of the PoP1.]

Personnel and Team: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

Non-traditional defense contractor, nonprofit research institution, or 1/3 cost sharing: [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement.]

Period of Performance: [Indicate the total proposed PoP1.]

Cost Share: [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are **encouraged** to discuss the ability to bring leveraged funding/cost share to complete the project goals.]

Rough Order Magnitude (ROM) Pricing: [The Offeror must provide an estimate based on the technical approach proposed in the White Paper. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required for PoP1 of up to 24 months to advance the project. The following ROM pricing shall be included in the White Paper. (**NOTE: If invited to Stage 2, it is preferred that the total cost to the Government proposed in the ROM not substantially deviate from the proposed cost presented in the full proposal (unless otherwise directed by the Government) as this may result in an unacceptable rating.) Use the example table format and template below to provide the ROM pricing.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table. If selected for award, a full cost proposal will be requested.

	Year 1	***Year 2***	***Year 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*	*$ 100,000.00*	***$ 300,000.00***
Labor Hours	*1,000.0 hrs*	*1,000.0 hrs*	*1,000.0 hrs*	***3,000.0 hrs***
Subcontractors	*$ 50,000.00*	*$ 50,000.00*	*$ 50,000.00*	***$ 150,000.00***
Subcontractors Hours	*500.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	*$0.00*	*$0.00*	*$0.00*	***$0.00***
Gov't/Military Prtnrs / subKTR Hours*	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	***0.0 hrs***
Consultants	*$ 10,000.00*	*$ 10,000.00*		***$ 30,000.00***
Consultants Hours	*100.0 hrs*		*.0 hrs*	***300.0 hrs***
Material/Equipment	*$ 75,000.00*		*$ 75,000.00*	***$ 225,000.00***

EXAMPLE

Other Direct Costs (ODC)	*$ 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 row above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System (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.

****Offerors are reminded to refer to the Selection Criteria under Section 5 of the RPP to ensure that all required information is provided.**

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: 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 Government Purpose Rights or 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 2: 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 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.

Addendum 1 – Technology/Knowledge Readiness Level Checklist

TRLs provide a systematic way to assess and communicate the level of maturity of a particular technology or combination of technology as it relates to product development across different types of technologies. Full definitions of TRLs can be found here. 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 22-08-BDA, the Offeror shall use only the appropriate checklist that aligns with the type of prototype outlined below:

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

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

Checklist 1: 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 2: 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 3: 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 4: 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 – Technical Addendum for the Subsequent PoP Work (PoP2)

For Information Only - Stage 2 Requirement

General Instruction: As noted in Section 2.2 of the RPP, an additional $5M of funding may be available for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP2 after the Go/No-go Decision Point. The PoP2 work will be dependent on the advancement in prototype maturity of the prototype at the end of the base PoP1 of up to 24 months, as it applies to each resultant award(s). Examples of PoP2 tasks are listed in Section 3 of the RPP. Although awards in response to this RPP will initially focus on the scope of work for the first 24 months, this addendum is intended to provide the Sponsor with information on the Offeror's plan for work beyond the base PoP1. The following template is required for the Stage 2 Proposal.

Technical Tasks: [Specify the objective of each proposed follow-on task. 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.]

PoP: [Indicate the proposed PoP (duration) for the potential follow-on work in total.]

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

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed PoP2 work. List milestones and deliverables from the proposed PoP2 work.]

Participants: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the proposed follow-on tasks.]

Rough Order of Magnitude (ROM) Pricing:
[Indicate the ROM pricing (including indirect costs) **using the table format below**. The ROM table should include a column for each potential PoP2 task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required for each potential PoP2 task required to advance the project toward military fielding and/or production tasks. 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.]

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

Subcontractors Hours	*500.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	*$0.00*	*$0.00*	*$0.00*	***$0.00***
Gov't/Military Prtnrs / subKTR Hours*	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	***0.0 hrs***
Consultants	*$ 10,000.00*	*$ 10,000.00*		***$ 30,000.00***
Consultants Hours	*100.0 hrs*		*0.0 hrs*	***300.0 hrs***
Material/Equipment	*$ 75,000.00*		*$ 75,000.00*	***$ 225,000.00***
Other Direct Costs (ODC)		*$ 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 row above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System (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.