

Request for Project Proposals



Solicitation Number: MTEC-26-03-PROMPT
“PRimer and prObe Manufacturing PlaTform (PROMPT)”

Issued by:
Medical Technology Enterprise Consortium, Inc. (MTEC)
315 Sigma Drive
Summerville, SC 29486

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

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

For more information on the MTEC mission, see the MTEC website at mtec-sc.org.

MTEC, Inc. is a 501(c)(3) non-profit corporation that operates the MTEC under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC awarded under the authority of 10 U.S.C. § 4022. The term "prototype project" includes a project that addresses (A) a proof of concept, model, or process, including a business process, (B) reverse engineering to address obsolescence, (C) a pilot, novel application of commercial technologies for defense purposes, (D) agile development activity, (E) the creation, design, development, or demonstration of operational utility, or (F) any combination of the foregoing. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. For more information on the prototype definition, please see the Proposal Preparation Guide (PPG) located on the MTEC website at mtec-sc.org/proposal-submit.

1.2. Purpose

This solicitation, issued by the MTEC Consortium, represents a Request for Project Proposals (RPP) for MTEC in support of the Defense Threat Reduction Agency (DTRA). Military relevance is a critical component of the Solution Brief submission. Strategic oversight for the award(s) supported by this RPP will be provided by the Joint Science and Technology Office.

This RPP is focused on the development of a fully automated, man-portable, and ruggedized prototype platform for the on-demand, expeditionary manufacturing of clinical-quality nucleic acid primers and probes. This system must be designed for operation in far forward or austere environments by non-specialist personnel.

2 Administrative Overview

2.1. Request for Project Proposals

MTEC is utilizing a multi-staged acquisition approach for this RPP. This is intended to provide the Government with a robust form of evaluating the best solution. The following sections describe the formats and requirements of solution proposals. Additionally, the Proposal Preparation Guide (PPG) contains several templates required for this RPP. The PPG can be found on the MTEC website ([How to submit proposals](#)). Proposals that fail to follow the mandatory requirements may be eliminated from the competition during MTEC's preliminary screening stage (see Section 5 for more details on the Selection process).

In Stage 1 of this effort, Offerors are invited to submit Solution Briefs to describe their proposed solutions. Offerors who submit Solution Briefs in response to this RPP should submit by the date on the cover page of this RPP. Solution Briefs may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each Solution Brief submitted must be in accordance with the mandatory format provided in **Section 8 of the RPP**. Solution Briefs that fail to follow the mandatory format may be eliminated from the competition during

MTEC's preliminary screening stage (see **Section 5** for more details on the Selection process).

Note that the terms "Solution Brief" and "Proposal" are used interchangeably throughout this RPP.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) encourages Offerors to propose budgets commensurate with the nature, scope and complexity of the proposed research. Offerors should submit budgets that include the entire Period of Performance (PoP) of the research project. Yearly budgets should include all direct and indirect costs, based on supportable, verifiable estimates. Offerors are encouraged to scope out their budgets in alignment with major deliverables of their proposed work so that large budgets are easier to evaluate, and Sponsors can more easily allocate available funding.

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

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).

MTEC expects to make **one or more award(s)** to a qualified Offeror 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. See the "MTEC Member Teaming" section below for more details.

The PoP is not to exceed **24 months**.

2.3. Acquisition Approach

As noted above, MTEC is utilizing a multi-stage approach for this effort:

- **Stage 1 [Solution Brief]:** MTEC Members are invited to submit a Solution Brief using the format contained in **Section 8 of this RPP**. The Government will evaluate proposed solutions using the criteria listed in **Section 5.2 of this RPP**.
- **Stage 2 [Solution Brief Pitch]:** Offerors who are favorably evaluated during Stage 1- Solution Brief will be invited to present and discuss their proposed solution with the Government sponsors via a pitch event. Pitches are expected to include introductions to the proposed project along with a SOW/Milestone Payment Schedule and cost information. The Government will evaluate these pitches using the criteria listed in **Section 5.3 of this RPP**.
- **Stage 3 [Selection for Award]:** Upon completion of the Government's evaluation, Offeror(s) will be notified of the final award decision. Those Offeror(s) selected for award will be invited to submit a detailed Cost Proposal in accordance with the MTEC PPG.

The due date for Solution Briefs is found on the **cover page of this RPP**. Solution Briefs may not be considered under this RPP unless the Solution Brief was received on or before the due date specified on the cover page.

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the OTA for prototype projects Number W81XWH-15-9-0001 with MTEC administered by MTEC. MTEC will negotiate and execute a Base Agreement with its 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/documents-library/.

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 proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with MTEC, then the Offeror must state on the cover page of its proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.4. Offeror Eligibility

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

2.5. Proprietary Information

MTEC will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. MTEC 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 PPG, please mark all confidential or proprietary information as such.**

MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit proposals or receive any research project funding through MTEC.

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 operate in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Therefore, on your proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your proposal for the purpose of engaging in outreach activities with these private entities.

2.6. Proposers Conference

MTEC intends to host a Proposers Conference that will be conducted via virtual webinar on **Wednesday, July 8th at 2PM EST**. 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 of this RPP. To register for this conference, please use the following link:

<https://events.gov.teams.microsoft.us/event/36cf8b7c-e796-4707-b437-7736163c038e@83251a03-76a5-4450-8bd6-55962891f972>

2.7. MTEC Member Teaming

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

MTEC's new website features a new functionality to assist members in team building. MTEC's New Member Profiles can help Offerors identify potential teaming partners among other MTEC members, including innovators, and service providers. It can be accessed via www.mtec-sc.org/members.

MTEC also intends to hold a Teaming Connect for this effort on **Tuesday, July 14 at 2pm EST**. This will be a virtual "connect" session via webinar to help the membership collaborate and partner in relation to specific focus areas listed in the RPP. Organizations that are interested in speaking at this teaming connect and will be allotted three (3) minutes to pitch accompanied by a (1) slide. To register for this conference, please use the following link: <https://events.gov.teams.microsoft.us/event/36cf8b7c-e796-4707-b437-7736163c038e@83251a03-76a5-4450-8bd6-55962891f972>

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

2.8. Cost Sharing

Cost sharing is defined as the non-Federal resources expended by the award recipients on the proposed Statement of Work (SOW). Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP. In order to be compliant with 10 U.S.C. § 4022, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award. Additionally, **Section 7.4 of the PPG** contains information on cost share definitions and directions for inclusion.

2.9. MTEC Assessment Fee

Per the Consortium Member Agreement, each recipient of a RPA under the MTEC OTA shall pay MTEC an amount equal to 2% of the total funded value of each research project awarded. Such deposits shall be due no later than 90 days after the RPA is executed. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other 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

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

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically negotiated IP and Data Rights terms herein. **It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each RPA shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of Stage 1 of the RPP process (submission of proposals), 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, MTEC 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 PoP beginning December 2026 (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via MTEC and prior to issuing a Research Project Award.

2.12. Anticipated Solutions Brief Selection Notification

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

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

3 Technical Requirements

3.1 Background

Technology development and progress is urgently needed to address critical capability gaps in expeditionary medical diagnostics. Current diagnostic capabilities are hindered by a reliance on centralized manufacturing for essential nucleic acid amplification test (NAAT) reagents, such as primers and probes. This paradigm is currently incompatible with the demands of agile, far-forward medical responses to novel biothreats. An effective prototype must overcome several key challenges identified across the current landscape. Technologically, it must replace the current hazardous and environmentally sensitive synthesis systems with field-stable chemistry and ruggedized hardware. Any proposed system must integrate a deployable, effective method for both the purification of synthesized reagents and their subsequent quality control and validation, as this represents a major unsolved problem. Finally, any successful prototype must be developed with a clear strategy to navigate the currently undefined regulatory pathway for far-forward manufactured diagnostics.

3.2 Objective

The primary objective is to develop, integrate, and demonstrate a fully automated, man-portable, and ruggedized prototype platform for the on-demand, expeditionary manufacturing of clinical-quality nucleic acid primers and probes. This system must be designed for operation in far forward or austere environments by non-specialist personnel. The capability will specifically address critical technology gaps by replacing traditional hazardous synthesis chemistry with a field-stable alternative and, most critically, integrating novel, on-board capabilities for both the automated purification and quality control validation of the resulting reagents. The successful outcome will be a self-contained system capable of producing sequence-verified, high-purity oligonucleotides from a digital sequence file within hours, thereby enabling a rapid, decentralized diagnostic response to novel biothreats without reliance on traditional laboratory infrastructure or cold chain logistics.

3.3 Solution Requirements

The USG is seeking solutions capable of satisfying the following capabilities:

- Integrate nucleic acid synthesis of Polymerase Chain Reaction (PCR) primers and probes, their basic purification, and first line quality control into compact, ruggedized instruments optimized for reduced size, weight, and power, and operable by minimally trained personnel at forward roles of care. The

instrument should be designed to meet MIL-STD-810 testing requirements (temperature, humidity, shock, vibration) and have reduced power draw for battery operations. Minimize logistical requirements for synthesis in inert environments through miniaturization, cartridges, or gas generation *in situ*.

- Provide high coupling efficiency oligonucleotide synthesis suitable for at least 20–40 nucleotide (nt) PCR primers and fluorescent probes, using chemistries (phosphoramidite and/or enzymatic) that can be operated safely in low-resource/field condition environments. Reagents must demonstrate stability at room temperature (20–25°C) for at least 12 months and function reliably across –20°C to 55°C without cold-chain dependence, utilizing approaches such as on-demand phosphoramidite synthesis, lyophilized formulations, or engineered enzymatic systems with enhanced thermostability. This should include the use of reagent, solvent, and cartridge designs that minimize the cold chain dependence, flammable solvent volumes, and hazardous materials.
- Improve oligonucleotide production time and yield to enable production of higher concentrations and volumes, ideally generating multiple high-quality nucleic acid-based molecular assay reagents per synthesis run to support rapid development of laboratory-developed tests.
- Provide purification and verification approaches, such as cartridge-based cleanup and microfluidic electrophoresis, which are comparable to gold standard methods (HPLC, LCMS) in higher resource laboratories.
- Demonstrate end-to-end workflows through pilot projects that replicate a commercial PCR assay, comparing field-manufactured primers/probes to Good Manufacturing Practices (GMP) equivalents in terms of purity, analytical performance, and diagnostic accuracy. Prototypes must be provided for independent evaluation by government-identified laboratories synthesizing panels of relevant oligonucleotide sequences in a controlled environment.

3.4 Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the initial PoP. Follow-on work may include nonclinical studies required for the technical data package for a regulatory application; establish robust quality system; improve efficiency and reproducibility of manufacturing process for scale up; work towards regulatory clearance/ approval; military environmental and operational assessments; ruggedization for operation in military environments; and advanced technical testing in relevant or simulated operational environments.

4 Solution Brief Preparation and Process

4.1. Solution Brief Submission

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: <https://bids.mtec-sc.org/>. Include the **MTEC-26-03-PROMPT** on each Solution Brief submitted. Information on registering and submitting through the BIDS portal can be found on our website (<https://mtec-sc.org/proposal-submit>).

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline. **MTEC 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.**

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are

encouraged to contact the Points-of-Contact (POCs) identified herein until the Proposal due date/time to clarify requirements (both administrative and technical in nature).

4.2. Instructions for the Preparation of the Stage 1 Solution Brief

Offerors submitting Solution Briefs in response to this RPP should prepare all documents in accordance with the following instructions:

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

Required Submission Documents (6): Submitted via BIDS. Individual submission documents must be 5MB or lower.

- **Solution Brief:** One Word or PDF document (Required template is provided in **Section 8 of this RPP**)
- **Warranties and Representations:** one Word or PDF document (**See Attachment 3 of the PPG**)
- **Current and Pending Support:** one Word or PDF document (**Attachment 5 of the PPG**)
- **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**See Attachment 6 of the PPG**)
- **Letters of Support (if applicable):** one Word or PDF document (no template provided)

Solution Briefs must be prepared **according to the mandatory format provided in Section 8** of this RPP. The Solution Brief is **limited to seven pages (plus a cover page for a total of eight pages)**. References may be included in the Solution Brief and are **excluded** from the page limitation. Appendices are also **excluded** from the page limitation. Formatting requirements include 11-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. **Solution Briefs exceeding the page limit may not be accepted.**

FOR INFORMATION ONLY: Additional attachments/appendices (henceforth referred to as supplemental information) to the Solution Brief submission may be requested after completion of the Stage 1 Solution Brief evaluation. The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the Stage 1 evaluation summary is provided.

4.3. Instructions for the Preparation of the Stage 2 Solution Brief Pitch

Upon review of the Solution Briefs, Offerors may be invited into Stage 2 of this effort. Offerors that are recommended for Stage 2 will receive notification letters which serve as formal requests for Stage 2 (Solution Brief Pitches) and may contain requested revisions or supplemental information. These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (2): Submitted via BIDS. Individual submission documents must be 5MB or lower.

- 1) **Solution Pitch:** One PDF document.
- 2) **Statement of Work:** One Word or PDF document (**See Attachment 4 of the PPG**)

In Stage 2, the Offeror(s) will provide a virtual “pitch” of the proposed project during a meeting with the Government. The solution brief pitch should provide more details about the proposed technology outlined in

Stage 1 (Solution Brief). The information discussed during the solution brief pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the proposal and the Offeror's capabilities. The solution brief pitch should be restricted to **a maximum of 20 minutes for the presentation by the Offeror with a total time of 45 minutes** to include questions from the Government. Any materials that will be presented during the solution brief pitch or included as supplementary material must be provided in advance of the meeting date. Briefing slides or documents or a combination thereof can be used to support this effort.

The Solution Brief Pitch is expected to include the following:

- **Technology Description and Approach:** A more robust description of the technology, approach and emphasize why this approach is expected to result in a successful outcome. This discussion should include relevance to the military use cases.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory pathway (as applicable), indication of use and designation, strategy for obtaining regulatory approvals or clearances. Offerors are also encouraged to include costs associated with their development strategy.
- **Interoperability:** The Offeror will convey details related to product interoperability with compatible systems and plans for future data set generation.
- **Relevant Experience:** The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the program objective and solution requirements described in Section 3 of this RPP and build confidence in the team's capabilities.
- **Effectiveness (Opportunity and Risk):** The Offeror will identify, assess, evaluate, and clearly convey items for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project measure, and the mitigation plan for each identified risk item.
- **Partnerships/Collaborations:** The Offeror will describe any current or potential partnerships or collaborations that may be of use when developing this product, especially in regards to synthetic data set development. Partnering with Government laboratories may be required downstream.
- **Competitive Advantage:** A clearly defined competitive advantage of the proposed solution over already existing solutions and other solutions in development by others in the field.
- **Military Transition:** Offeror will describe the pathway to developing this into a product that can be used by the military.

4.4. Instructions for the Preparation of the Stage 3 Selection for Award

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

Required Submission Documents (2) (Submit to contracts@mtec-sc.org):

- **Section I: Cost Proposal Narrative as one Word or PDF document.**
- **Section II: Cost Proposal Formats as one Excel or PDF document.**

See the PPG for additional instructions for submission requirements. Also refer to **Attachment 7 of the PPG** for details on how the full Cost Proposals will be evaluated.

5 Selection

5.1. General Information

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Evaluations at all stages of the Solution Brief acquisition process shall be based on an independent, comprehensive review and assessment of the work proposed against stated evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The Solution Brief and/or the Solution Brief Pitch process may involve the use of contractors as subject matter experts (SME) serving as nongovernmental advisors. Where appropriate, MTEC will employ NDAs to protect information contained in submissions. 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 as outlined in Section 2.6. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 1.

| TABLE 1- 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. |

In support of this multi-stage acquisition approach, the Government sponsor will perform proposal source selection at each stage of the process. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. Upon completion of Stage 2, the Source Selection Authority may:

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

In rare cases, the following recommendation may be provided: "Recommendation Undetermined." This is reserved for situations in which additional information/documentation is needed by the Government evaluators before finalizing a recommendation to one of those listed above and is intended to facilitate the release of all evaluator comments within the BIDS System.

5.2. Solution Brief (Stage 1) - Selection and Evaluation Process

MTEC will distribute all Proposals that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 (Solution Brief Pitch) based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Proposals against established criteria to determine technical merit. Regardless of whether the evaluation includes a peer review, all Solution Briefs will be evaluated based on the following factors. Feedback will be provided to the Offerors.

Stage 1 - Solution Brief Evaluation Factors (of equal importance):

- 1. Programmatic and Technical Relevance**
- 2. Personnel and Team Expertise**

Evaluation Factor 1 – Programmatic and Technical Relevance: The Offeror’s proposal will be assessed for the extent at which the following are satisfied:

- **Military Relevance:** The degree to which the Offeror demonstrates a strong solution to the defined unmet military medical need, specifically the alignment to project aims described in Section 3 of this RPP.
- **Technical Merit:** The degree to which the Offeror presents an approach to synthetic data generation with strong supporting methods and a competitive advantage that is relevant and appropriate for future use in austere, tactical environments.

Evaluation Factor 2 – Personnel and Team Expertise: This factor will evaluate the strength of the organization/team proposed to complete the work. The Offeror’s resources (key facilities, equipment, etc.), project management plan, expertise, and experience of personnel may be considered as part of this factor. It will also address the Offeror’s experience fielding identified analogous solutions and experience with military medical solutions and projects.

5.3. Solution Brief Pitch (Stage 2) - Selection and Evaluation Process

Offerors invited to Stage 2 (Solution Brief Pitch) will then be evaluated by a judging panel assembled by the Government Sponsor. The judging panel will make recommendations for award. This pitch is anticipated to take place virtually, using Microsoft teams.

Stage 2 - Solution Brief Pitch Evaluation Factors (of equal importance):

- 1. Technical Feasibility**
- 2. Potential for Scalability and Sustainment**

Evaluation Factor 1 – Technical Feasibility: This factor will evaluate the feasibility of the proposed solution and its alignment with the RPP’s topic area. This factor will also include evaluation of the Offeror’s risk mitigation plan to successfully implement the proposed solution (e.g., proposer has a demonstrated plan, resources, and capabilities to implement the proposed solution).

Evaluation Factor 2 – Potential for Commercialization and Transition: The Offeror’s proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal. Any of the following information may be assessed (if applicable to the proposed project):

- **Technical Maturity Advancement:** The degree to which the Offeror proposes to advance the technical maturity level during the performance of the project and advance the technology to the next level of development, from a technical and financial perspective. As such, the Government may evaluate how well the funding strategy supports that advancement.

- Market and Business Model: Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.
- Development Strategy (including timing and regulatory): Feasibility of the Offeror's product development strategy, including any required regulatory pathway. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

5.4. 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 during the demonstration.

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 during the demonstration.

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

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

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

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

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

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

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

6 Points-of-Contact

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

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

7 Acronyms/Abbreviations

| | |
|------|---------------------------------------|
| BIDS | System for Submission of the Solution |
| CSV | Comma Separated Values |
| DHA | Defense Health Agency |

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| | |
|---------|--|
| DoD/DoW | Department of Defense/Department of War |
| DTRA | Defense Threat Reduction Agency |
| GMP | Good Manufacturing Practices |
| HPLC | High Performance Liquid Chromatography |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| LCMS | Liquid Chromatography Mass Spectrometry |
| MTEC | Medical Technology Enterprise Consortium |
| NAAT | Nucleic Acid Amplification Test |
| NDA | Non-disclosure Agreement |
| Nt | nucleotide |
| OCI | Organizational Conflict of Interest |
| OTA | Other Transaction Agreement |
| PCR | Polymerase Chain Reaction |
| PDF | Portable Document Format |
| POC | Point of Contact |
| PoP | Period of Performance |
| PPG | Proposal Preparation Guide |
| PROMPT | Primer and probe Manufacturing PlaTform |
| ROM | Rough Order Magnitude |
| RPA | Research Project Award |
| RPP | Request for Project Proposals |
| SME | Subject Matter Expert |
| SOW | Statement of Work |
| UEI | Unique Entity Identifier |
| USAMRDC | U.S. Army Medical Research and Development Command |
| U.S.C. | U.S. Code |
| USG | U.S. Government, specifically the DoW |

8 Solution Brief Template

Cover Page

[Name of Offeror]

[Address of Offeror]

[Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #]

CAGE code: [CAGE code]

[Title of Solution Brief]

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

[A proprietary data disclosure statement if proprietary data is included. Sample: **This Solution Brief includes data that shall not be disclosed outside MTEC and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Solution Brief and negotiate any subsequent award. If, however, an award agreement is a result of, or in connection with, the submission of this data, MTEC and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit MTEC and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).**]

Willingness to allow MTEC Officers access to your Solution Brief 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 proposals within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your proposal for the purposes of engaging in outreach activities with these private sector entities. MTEC staff have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]**

[Title of Solution Brief]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a robust description of the proposed solution.
- Emphasize how the proposed solution meets the overall objective specified in this RPP.

Scientific Rationale / Preliminary Data

- Demonstrate how your proposed solution currently meets the Technical Requirements described in **Section 3.3**.
- Include previous studies or preliminary data that support the feasibility of the proposed solution set.

Proposed Project Plan and Follow-on Work

- Describe the research methodologies utilized in designing and developing,
- Demonstrate the ability to further advance the project maturity beyond the proposed PoP.
- Highlight the potential capabilities that can be explored/achieved through short term and/or long-term advancement of the project in a way that is beneficial to the Government.
- Discuss potential refinements their solution set with the following use cases in mind: (1) single caregiver and casualty; (2) multiple caregivers and causalities; (3) mass causality use cases and (4) enroute and higher echelons of care.

Team

- Describe the qualifications and expertise of the key personnel and organizations associated with the proposed project.
- Detail any past performance(s) that demonstrate relevance to the program objective and solution requirements.

Resources

- Identify any key facilities, equipment, and other resources relevant for the technical solution being proposed.
- Describe any current or potential partnerships or collaborations that may be of use when developing this product, especially regarding synthetic data generation.

Transition to the Government

- Describe previous/existing partnerships with industry or the USG/DoD (including any resultant contracts/grants/awards and/or IP).
- Describe the plan to transition the technology to the military market for government use/implementation.

Product Development Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required).
- Include any information or plans for product interoperability with established military health systems.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military.
- Offerors are required to include costs associated with their development strategy (Rough Order Magnitude [ROM] costs).

Risk Identification and Mitigation

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

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

Appendix 1: Warranties and Representations: (template provided in Attachment 3 of the PPG)

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

Appendix 2: Current and Pending Support (template provided in Attachment 5 of the PPG)

- Summarize other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request. If there is no current and/or pending support, enter “None.”

Appendix 3: Intellectual Property and Data Rights Assertions (template provided in Attachment 6 of the PPG)

- The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 4: Letter of Support (no template provided)

- Include any letters of support from relevant sources regarding the proposed solution or teaming arrangements.