Request for Prototype Projects
Under

Medical CBRN Defense Consortium (MCDC)
Other Transaction Agreement (OTA)
Number: W15QKN-16-9-1002

Solicitation Number: RPP-25-01

Issued by:

Advanced Technology International (ATI)
MCDC Management Firm
315 Sigma Drive
Summerville, SC 29486

For the
Joint Program Executive Office for
Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND)

Through the
Army Contracting Command – New Jersey
Picatinny Arsenal, NJ 07806-5000

MCDC 25-01
Innovative Drug Development Pipeline Methods for Rapid Medical Countermeasure (MCM) Development

Request Issue Date: 17 October 2024

Enhanced White Paper Due Date: 28 October 2024 - 12:00 PM Eastern Time

Medical CBRN Defense Consortium
Other Transaction Agreement

Request for Prototype Projects

Solicitation Number: RPP-25-01

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1 General

1.1 Purpose

This solicitation, issued by Army Contracting Command – New Jersey (ACC-NJ), represents a Request for Prototype Proposals (RPP) from the Medical CBRN Defense Consortium (MCDC), in support of the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND).

The RPP is a request for **Enhanced White Papers ONLY**. Enhanced White Papers must be submitted in the format described in Appendix I, Mandatory Enhanced White Paper Template. The Government will make a source selection decision based on the Enhanced White Paper. The Offeror will be provided feedback once the evaluations have been completed for the requirement under which the Enhanced White Paper was submitted.

The MCDC Member(s) selected for award and the Government Technical POC can collaborate and jointly refine the draft Statement of Work (SOW) that was submitted in response to the RPP. Once the SOW is finalized, the MCDC Consortium Management Firm (CMF), Advanced Technology International (ATI), will request a detailed cost proposal in accordance with Appendix III, MCDC Award Process and Requirements. An Offeror's submission of an Enhanced White Paper under this RPP indicates concurrence with providing the information requested in Appendix III, should the Offeror be selected for award.

All eligible Offerors may submit Enhanced White Papers for evaluation, according to the criteria set forth herein. Offerors are advised that only ATI, as the MCDC's CMF, with the approval of the Government's Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Prototype Projects as result of this RPP.

In accordance with 10 U.S.C. 4022(f), and upon a determination that the prototype project for this transaction has been successfully completed, any competitively awarded prototype OTA as a result of this RPP, may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

1.2 Type of Funding Instrument Issued

The Government-selected projects will be funded under the Other Transaction Agreement W15QKN-16-9-1002 with the MCDC, which is administered by the CMF, ATI. The CMF will negotiate and execute a Base Agreement with MCDC members. This agreement is governed by the same provisions as the OTA between the Government and MCDC. Subsequently, any project that is selected for award will be funded through a Project Agreement issued under the Base Agreement. A copy of the Base Agreement may be found on the Members Only portion of the MCDC website at https://www.medcbrn.org. At the time of the submission, Offerors must certify on the cover page of their Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MCDC Base Agreement.

Offerors are advised to contact the CMF if they have any questions regarding this requirement. Offerors are also advised to check the MCDC website periodically during the enhanced white paper preparation period for any new changes to the Base Agreement terms and conditions. As practicable, changes will be electronically forwarded to the MCDC Member Organizations prior to posting.

1.3 Non-Government Personnel

The CMF will oversee the submission of Enhanced White Papers in response to this RPP, and review cost proposals submitted if selected for award, as described in Appendix III, MCDC Award Process and Requirements. The MCDC Membership Agreement contains a proprietary information agreement as an

attachment, which requires the CMF to protect the MCDC Member's proprietary information. The CMF shall take the necessary steps to protect all proprietary information, and shall not use such proprietary information for any purpose other than agreement administration if the effort is selected for award. An Offeror's submission of an Enhanced White Paper under this RPP indicates concurrence with the aforementioned CMF responsibilities.

Additionally, the Government may use Contractor Support Personnel (CSP). The CSP will be required to submit to the Government a Non-Disclosure Agreement reflecting the effort(s) that they will be supporting. The Offeror's submission of an Enhanced White Paper under this RPP indicates concurrence with the aforementioned use of CSP.

Finally, the MCDC Leadership may be provided, at their request, top-level data and metrics on Enhanced White Paper submissions for their use in monitoring the effectiveness of MCDC processes and the level of participation by MCDC members in the RPP. Information will only be released with Government approval. An Offeror's submission of an Enhanced White Paper under this RPP indicates concurrence with the aforementioned release of information to the MCDC Leadership.

1.4 Eligibility

Only those members of the MCDC who have executed the MCDC Member Agreement (CMA) and are deemed to be "Members in Good Standing" prior to the due date for Enhanced White Papers, will be eligible to have their submissions evaluated. An Offeror that submits an Enhanced White Paper prior to executing the CMA or is not a "Member in Good Standing," does so solely at its own risk, and neither the CMF nor the Government has any responsibility for costs associated with such a submission.

1.5 Other Transaction Authority

In accordance with Section 4022 of Title 10, Amendments to Other Transaction Authority, of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, each Prototype Project awarded under an OTA must meet at least one of the following conditions:

- There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

Throughout the period of performance of any Project Agreement, the Government will actively monitor the award to ensure compliance with this provision in accordance with implementation guidance from Headquarters – Department of the Army (HQDA) and/or Office of the Secretary of Defense (OSD). Offerors will be given the opportunity to become compliant with the guidance should they be found non-compliant. Failure to comply may result in termination.

For the purposes of the Enhanced White Paper, the Offeror must explain its approach on how the Offeror intends to comply with this requirement. The signed Affirmation of Business Status Certification and Supplement are NOT required with the Enhanced White Paper submission, but will be required if selected for award.

1.5.1 Nontraditional Defense Contractor Definition

A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section. A nontraditional defense contractor or nonprofit research institution can be a prime contractor, team member, subcontractor, lower tier vendor, or "intra-company" business unit, provided the business unit makes a significant contribution to the initiative (i.e., is a key participant). Examples of what might be considered a significant contribution include supplying new key technology or products, accomplishing a significant amount of the effort, or in some other way causing a material reduction in the cost or schedule or increase in the performance. Please note that there is both a quantitative and qualitative aspect to nontraditional defense contractor or nonprofit research institution participation, and the lack of one aspect may require a more significant contribution in the other. The significance of the nontraditional defense contractor or nonprofit research institution participation must be explained in detail in the signed **Affirmation of Business Status Certification and Supplement**. Inadequate detail can cause delay in award, or lead to ineligibility for award.

The MCDC will follow the specific guidance from OSD concerning the use of nontraditional defense contractors or nonprofit research institutions. Nontraditional defense contractors or nonprofit research institutions will be required to provide a UEI number. Any Offeror that does not fall within the parameters of the nontraditional defense contractor definition shall be considered a traditional defense contractor.

1.5.2 Resource Sharing Definition and Requirements

Resource sharing is defined as the resources expended by a party other than the federal Government in performance of the proposed SOW and subject to the direction of the Government. Resource sharing includes any costs a reasonable person would incur (necessary to) carrying out the work detailed in the SOW, but does not involve funds directly to the Government. If an initiative does not contain at least one nontraditional defense contractor participating to a significant extent, then it is required that the proposal contains at least one-third of the total initiative cost as a resource share.

1.6 Enhanced White Paper Response Date/Time

All Enhanced White Papers must be received by the Enhanced White Paper response date on the first page of this RPP, unless modified in an amendment to this RPP. Enhanced White Papers must be received by the due date/time to be considered for award. Enhanced White Papers received after the response date/time shall not be considered for evaluation and funding.

1.7 Other Special Requirements

1.7.1 Offerors are advised that research findings and technology developments arising from this RPP may constitute a significant enhancement to the national defense and to the economic vitality of the United States. As such, in the conduct of all work under the Base Agreement and subsequent Project Agreement(s), the MCDC Member will comply strictly with the International Traffic in Arms Regulation (22 CFR 120-130), the National Industrial Security Program Operating Manual (DoD 5220.22-M), and the Department of Commerce Export Regulation (15 CFR 730-774).

1.7.2 Offerors are further advised that the Project Agreement Holders shall comply with DFARS 252.204-7012: Safeguarding Covered Defense Information and Cyber Incident Reporting (October 2016).

1.7.3 Data Rights and Copyrights: The following provisions, as negotiated, will be incorporated into the Offerors' final Statement of Work.

1.7.3.1 Patent Rights

Background Intellectual Property. The Parties acknowledge that they have background intellectual property as follows:

Government Background Inventions. [To be furnished by Government prior to award.]
Contractor Background Inventions. [To be furnished by Contractor prior to award.]

Unless specified otherwise in this agreement, no party relinquishes rights to any background patents to any other party under this agreement. Additionally, no party to the awarded agreement shall enter into an agreement with any contract manufacturer or other third party whereby the third party will obtain rights in Subject Inventions or Subject Data, as those terms are defined in Other Transaction Agreement number W15QKN-16-9-1002, absent the mutual consent of the parties to the awarded agreement.

Article X, §B ("Allocation of Principal Rights") and §E ("Minimum Rights to the MCDC PAH and Protection of the MCDC PAH's Right to File") of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended for the purpose of this Project Agreement as follows:

a) **Subject Inventions. Grants of Non-Exclusive License to Subject Inventions.** Any Subject Invention[1] that is Made by a party under this agreement will be owned by the party having Made the invention. For each Subject Invention Made solely by the Contractor, the Government will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention and the right to sublicense same to third parties to practice the invention for any purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. For any Subject Invention Made solely by the Government, the Contractor will receive a non-exclusive, worldwide, transferable, paid-up, royalty-free, irrevocable license to practice the invention or allow a third party to practice the invention for any purpose.

b) **Grant of Rights of First Refusal to Exclusive License of Subject Invention.** For each Subject Invention Made solely by the Contractor, the Contractor shall provide the Government a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to no less than a fifty percent (50%) share of royalty based on gross royalty revenue received by the Government. For each Subject Invention Made solely by the Government, the Government shall provide a right of first refusal for an exclusive license to the Subject Invention, within a commercially reasonable time prior to the offer of license to any third party, and subject to a reasonable share of royalty income

[1] "Subject Invention" is hereby redefined as "any invention of the Government, PAH, or developed jointly by the parties, that was conceived or first actually reduced to practice in the performance of work under this Agreement."

and subject to a retention of Government use for research purposes only, for purposes of FDA licensure of the technology described herein, limited to the field of use described in the product indication, subject to a termination terms substantially similar to the events described in Section 1.7.3.3 below:

c) **Joint Inventions.** Any Subject Invention Made jointly by the Contractor and any Government employee shall be jointly owned by the Parties. The Contractor shall have the first option to prepare and file the patent application(s) covering the Subject Invention, at its own expense. In the event that the Contractor declines to file or complete prosecution of such patent application at its own expense in a timely manner, the Contractor waives its co-ownership interest therein, and agrees to assign its full right, title and interest to such joint Subject Invention to the Government, so as to allow the Government to prepare, file or continue prosecution of such patent application(s), in exchange for a non-exclusive, irrevocable, transferable, paid-up license to practice such Subject Invention throughout the world. In the event that the Contractor elects to file and complete prosecution of such patent applications, the Government shall receive a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention, have the invention practiced throughout the world by or on behalf of the Government, and sublicense the invention to third parties for any purpose, including but not limited to continuing research and development related to the Subject Invention, and eventual regulatory approval and commercialization thereof. The Contractor will receive a right of first refusal for an exclusive license to the subject joint invention upon terms identified in Section 1.7.3.1(b) above.

d) **Filing of Patent Applications.** The party having the right to retain title to, and file patent applications on, a specific Subject Invention may elect not to file patent applications, provided it so advises the other party within ninety (90) days from the date it reports the Subject Invention to the other party, or at least ninety (90) days before a statutory bar date or public disclosure, whichever occurs earlier. Thereafter, the other party may elect to file patent applications on the Subject Invention and the party initially reporting the Subject Invention agrees to assign its ownership interest in the Subject Invention to the other party.

e) **Patent Expenses.** The expenses attendant to the filing of patent applications shall be borne by the party filing and/or prosecuting the patent application. Each party shall provide the other party with copies of the patent applications it files on any Subject Invention, along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office. The Parties agree to reasonably cooperate with each other in the preparation and filing of patent applications resulting from this agreement.

f) **Relationship to Base OTA Patent Terms.** If there is a conflict between this Section and Article X of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article X of W15QKN-16-9-1002, those sections remain operative.

1.7.3.2 Data Rights

Article XI, §C of Other Transaction Agreement number W15QKN-16-9-1002, is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§A(12) and (C)(4), as follows:

a) **Subject Data Ownership.** Subject Data (defined as Technical Data under Article XI, §A(13), generated, directly or indirectly, related to the work performed under this agreement) shall be jointly owned by the Parties. Each party, upon request to the other party, shall have the right to review and to request delivery of all Subject Data, and delivery shall be made to the requesting party within two (2) weeks of the request, except to the extent that such Subject Data are subject to a claim of confidentiality or privilege by a third party. All Deliverables, as described in the Deliverable Table within the Statement of Work, or mentioned elsewhere in this document, are considered Subject Data under this agreement.

b) **Confidential Information.** Neither Party, as the Receiving Party, shall, directly or indirectly, divulge or reveal to any person or entity any confidential information of the other Party without the Disclosing Party's prior written consent, or use such Confidential Information except as permitted under this agreement.

c) **Exclusion.** Such obligation of confidentiality shall not apply to information which the Receiving Party can demonstrate through competent evidence: (i) was at the time of disclosure in the public domain; (ii) has come into the public domain after disclosure through no breach of this agreement; (iii) was known to the Receiving Party prior to disclosure thereof by the Disclosing Party; (iv) was lawfully disclosed to the Receiving Party by a Third Party which was not under an obligation of confidence to the Disclosing Party with respect thereto; or (v) was approved for public release by prior written permission of the Disclosing Party.

d) **Background Technical Data Rights Assertions.** Contractor asserts background technical data rights as follows:

[Prior to award, Contractor to list and describe any technical data or computer software to be furnished with restrictions; the basis for assertion; asserted rights (Restricted, Limited, Government Purpose); name of organization asserting restrictions; and deliverable/WBS# affected.]

e) **Relationship to Base OTA Data Rights Terms.** If there is a conflict between this Section and Article XI of W15QKN-16-9-1002, the Project Agreement language will supersede and control the relationship of the parties. Where no modifications are made by this Section to the base terms in Article XI of W15QKN-16-9-1002, those sections remain operative.

1.7.3.3 Regulatory Rights

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected this agreement will result in the FDA clearance and commercialization of product(s) in Appendix II of this RPP (the "Technology"). The Project Agreement Holder (PAH) may be the Sponsor of the Regulatory Application (an Investigational New Drug Application (IND), Investigational Device Exemption (IDE), New Drug Application (NDA), Biologics

License Application (BLA), Pre-Market Approval Application (PMA), or 510(k) Pre-Market Notification Filing, or another regulatory filing submitted to FDA) that controls research under this agreement. If the PAH is the Sponsor of the Regulatory Application to FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), they have certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application.

The Senior Director Medical Regulatory (SDMR) is the JPEO-CBRND representative for all regulatory and quality activities. The PAH shall coordinate with the SDMR prior to communicating or meeting with the FDA, or other regulatory authorities, as appropriate. The PAH shall invite the SDMR to all FDA meetings and regulatory discussions applicable to this OTA Project.

This following clause protects the return on research and development investment made by the Government, in the event of certain regulatory product development failures related to the Technology.

The PAH agrees to the following:

a. The PAH will provide to the Government all data including top-line summaries and key conclusions from all studies supporting the regulatory filing and commercial approval to the extent that such data, summaries, and conclusions are funded by this Agreement. In addition, the PAH will offer the Government the opportunity to review and provide comments on a final draft of regulatory submissions which include data funded by this Agreement. The Government will review any such submissions promptly upon receipt. The PAH will reasonably consider any comments provided by the Government, and prior to submission will provide notification to the Government of any additional edits or revisions. The PAH will keep the Government apprised of planned FDA meetings and post-meeting outcomes relating to activities funded by this Agreement.

b. Communications. PAH will provide the Government with copies of all communications, both formal and informal, to or from FDA, regarding the Technology within 48 hours, and ensure that the Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

c. Non-compliance with section (a. & b.) may result in termination of the agreement.

d. Product Development Failure. Certain product development failures may trigger certain remedies in Section "e." below for the Government. These remedies is not available to the Government for any cause outside of the following:
    (i) this agreement is terminated for nonperformance,
    (ii) the PAH fails to obtain FDA approval within the operationally relevant timeframe determined by the Government after the award of this agreement (e.g., 3 years), when FDA approval is a requirement;
    (iii) the PAH fails to commercially market or provide an acceptable life cycle plan for continued supply of the Technology within three (3) years after FDA approval, licensure or clearance;
    (iv) the PAH gives notice, required to be submitted to the Government no later than thirty (30) business days, of any formal management

decision to terminate this product development effort pre-market or to file for Federal bankruptcy protection.

e. If any of the product development failures listed in Section "d." occur, the PAH, upon the request of the Government:
   (i) shall transfer possession, ownership and sponsorship or holdership of any Regulatory Application (including any associated expedited review designation, priority review voucher, or marketing exclusivity eligibility or award), regulatory correspondence, and supporting regulatory information related to the Technology, to the Government or its designee;
   (ii) shall inform FDA of the transfer of sponsorship or holdership of the Regulatory Application transferred under section (e)(i) above;
   (iii) shall negotiate in good faith a non-exclusive license, at customary industry rates and under reasonable terms and conditions, to any patent, copyright or other intellectual property owned or controlled by the PAH, developed prior to or outside the scope of this agreement, or any technical data that is necessary for the Government to pursue commercialization of this technology with a third party for sale to the Government or otherwise.

f. This clause will survive the acquisition or merger of the PAH by or with a third party. This clause will also be included in any subcontracts/sub-agreements relating to the development of the Technology. This clause will survive the expiration of this agreement.

g. **Public Law 115-92 Sponsor Authorization Letter**
The PAH shall submit to the Government, within thirty (30) days of project award, a fully executed sponsor authorization letter enabling FDA to disclose information to JPEO CBRND (or other Government customer) and its Government support contractors related to the proposed product under Public Law 115-92. A template for the sponsor authorization letter is attached as Exhibit 4.

JPEO CBRND (or other Government customer), in coordination with the PAH, shall formally submit the executed letter to the FDA under the Regulatory Application only if the proposed product becomes a DoD medical product priority under Public Law 115-92.

If the product becomes a DoD medical product priority, to the maximum extent practicable, JPEO CBRND (or other Government customer) will include the PAH in any and all meetings and correspondence conducted with the FDA under Public Law 115-92. If it is not practicable to include the Awardee in any Public Law 115-92 interaction with the FDA regarding the product (for example, discussions conducted at quarterly or semi-annual DoD-FDA meetings mandated by the Public Law), JPEO CBRND or (other Government customer) will provide a summary of the interaction to the PAH within ten (10) business days.

h. Deliverable(s): Public Law 115-92 Sponsor Authorization Letter.

2 Submission Requirements

2.1 Submission Deadline

The due date for Enhanced White Papers is no later than **the date specified on the cover page of this RPP**.

2.2 Enhanced White Paper Submission Instructions

2.2.1 Enhanced White Paper Format

Each Enhanced White Paper is limited to **15 pages plus a cover page (16 pages total), unless otherwise noted.** The following formatting requirements apply:

- 12 point font (or larger), single-spaced, single-sided, 21.6 x 27.9 cm (8.5 by 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 2.5 cm (1 inch).
- Enhanced White Papers must be submitted as a **MS Word (.docx or .doc) file or PDF (.pdf)** that is 5MB or less in file size.
- Enhanced White Papers shall be **UNCLASSIFIED**.
- Enhanced White Papers must be submitted using the secure upload link provided below:
  - ~~https://submissions1.ati.org/MCDC/BIDS.NSF/Start?ReadForm.~~ ~~https://ati.acqcenter.com/MCDC/BIDS.NSF/Start?ReadForm~~
    - Upon submission, a receipt confirmation including a unique reference number will be provided by email. The email will come from bidshelp@acqcenter.com (check your spam folder if you do not receive notification).

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2.2.2 Statement of Work Enclosure

A Statement of Work should be submitted as a separate attachment to the Enhanced White Paper. The Statement of Work template provided in Exhibit 3 is **MANDATORY**.

Statement of Work must be submitted as a MS Word (.docx or .doc) file that is 5MB or less in file size.

2.2.3 Enhanced White Paper Content

See Appendix I, Mandatory Enhanced White Paper Template, for complete information on Enhanced White Paper submissions. The Enhanced White Paper format provided is **MANDATORY**. Each Enhanced White Paper must address the Project Description/Statement of Objectives, and be in sufficient detail to permit a thorough evaluation from a technical perspective. The CMF will perform an initial screening to ensure compliance with the Enhanced White Paper format. The following items are primary reasons for non-compliance and elimination during this initial screening:

- Offeror does not meet membership eligibility requirements.
- Enhanced White Paper does not include an affirmative response on the cover page certifying to abide by the terms and conditions of the current Base Agreement (available on the MCDC website).
- Enhanced White Paper does not follow the Mandatory Template (Appendix I).
- Enhanced White Paper does not include an Estimate.
- Enhanced White Paper contains Classified material.
- Enhanced White Paper does not include a Statement of Work.
- Statement of Work does not follow the Mandatory Template (Exhibit 3).

2.3 Submission Preparation Cost

The cost of preparing Enhanced White Papers in response to this RPP shall not be considered a direct charge to any resulting award or any other contract.

3 Evaluation

3.1 Evaluation Process

All eligible Enhanced White Papers will be evaluated for award in accordance with the selection process described below. It is the Government's intention to negotiate, select and fund the "best value" project(s) from the submitted Enhanced White Papers. The ACC-NJ, with the assistance of the JPEO-CBRND, will conduct Enhanced White Paper Source Selection. Duplicate Enhanced White Paper submissions will not be evaluated or considered for award. Selections will be conducted in accordance with the evaluation criteria established in this Section. The Agreements Officer will make a determination whether to:

a) Select the Enhanced White Paper; or

b) Place the Enhanced White Paper in the "basket" if funding currently is unavailable; or

c) Reject the Enhanced White Paper (no award will be made based upon the submitted Enhanced White Paper).

The Agreements Officer's determination will be forwarded to the MCDC CMF to initiate the award process based on the availability of funding.

3.2 Basis of Selection (BOS)

A Basis of Selection will be prepared as a result of this RPP. The BOS will be an integrated assessment of each proposal evaluation to include the rating in accordance with the results of a technical benefit evaluation and a cost evaluation. The selection will be based upon the following two evaluation factors:

Technical Benefit
Cost Estimate

3.3 Technical Benefit

The overall Technical Benefit rating reflects the Government's confidence in the selected offeror's ability, as demonstrated in its enhanced white paper, to meet the stated objective.

Enhanced White Papers will be rated as follows:

Evaluation	Merit Rating
Enhanced White Paper meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses.	Outstanding
Enhanced White Paper meets requirements and indicates an adequate approach and understanding of the requirements. Proposal may contain weaknesses; however; these are offset by strengths.	Acceptable
Enhanced White Paper does not meet requirements and contains one or more deficiencies. Proposal is not awardable.	Unacceptable

An Enhanced White Paper that receives an overall Competitive Evaluation merit rating of Unacceptable will be rejected and will NOT be placed in the Basket. In addition, any Enhanced White Paper rated Unacceptable for the Technical Benefit Factor, will NOT receive an assessment of the cost estimate.

The overall Technical Benefit will be based on an integrated assessment of the below factors:

- Extent to which the Enhanced White Paper addresses the requirements outlined in the Statement of Objectives, and the likelihood of the proposed solution and approach to successfully achieve the stated requirements. This includes the ability to demonstrate past performance that can be leveraged to successfully meet the requirements.
- Extent to which potential risks are identified and mitigated.
- Extent to which the proposed schedule is realistic and conforms to the Government's planned schedule.

3.4 Cost Estimate

The Enhanced White Paper shall include as thorough a cost/price estimate as is possible. This estimate is part of the Competitive Evaluation process and will receive a narrative rating. The primary objective of this evaluation, at this time, are to assess (1) whether the project cost is within the available funding limits, and (2) the ability and/or likelihood of the Offeror to successfully execute the proposed project with the financial resources proposed. If a proposal is selected for award, a full cost proposal will be required as detailed in Appendix III, MCDC Award Process and Requirements. **NOTE: If the full cost proposal varies in any significant manner from the Enhanced White Paper Estimate, it may be grounds for the Government to reevaluate whether or not the project is suitable for award.**

The Government Technical Evaluators will determine if the overall estimate is deemed (I) Insufficient, (S) Sufficient, (E) Excessive, or Not Applicable (N/A).

3.4.1 Definitions

Insufficient (I) – The Estimate is lower than what is considered appropriate to successfully complete the proposed project.

Sufficient (S) – The Estimate is considered appropriate to successfully complete the proposed project.

Excessive (E) – The Estimate is higher than what is considered appropriate to successfully complete the proposed project.

Not Applicable (N/A) – The Estimate is not considered, as the Enhanced White Paper does not meet requirements, resulting in an Unacceptable technical benefit rating.

4 Points of Contact

Questions concerning this RPP should be directed to the MCDC Management Firm, ATI, 315 Sigma Drive, Summerville, SC 29486, E-mail contracts.mcdc@ati.org. Interested parties are encouraged to contact the specified point of contact at any time prior to proposal submission in order to obtain clarification and guidance.

Offerors are encouraged to contact the POC's identified in Appendix II up until the Enhanced White Paper submission due date with any questions or clarifications.

Once the RPP has closed, the status of the Enhanced White Paper submission cannot be discussed until the Competitive Evaluation process is complete.

Appendix I – Mandatory Enhanced White Paper Template

Separately attached.

Appendix II – Project Description/Statement of Objectives

1. 25-01 Innovative Drug Development Pipeline Methods for Rapid Medical Countermeasure (MCM) Development

Appendix III – MCDC Award Process and Requirements

Separately attached.

Exhibit 1 – MCDC ABSC Form

Separately attached.

Exhibit 2 – MCDC ABSC Form Supplement

Separately attached.

Exhibit 3 – MCDC SOW Template

Separately attached.

Exhibit 4 – Public Law 115-92 Sponsor Authorization Letter

Separately attached.

Exhibit 5 – Section 889 Prohibition Representation

If the Offeror is selected for award under this RPP, they will be required to submit a completed copy of the Section 889 Prohibition Representation prior to award. The representation is separately attached.