Request for Project Proposals



Solicitation Number: MTEC-24-04-AMDST

"Agile Medical Countermeasure Decision Support Tool (AMDST) Prototype"

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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for the
Medical Technology Enterprise Consortium (MTEC)

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

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

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 OTA Guide dated July 2023, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. For more information on the prototype definition, please see the Proposal Preparation Guide (PPG) located on the MTEC Members Only Site.

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 in support of the U.S. Defense Threat Reduction Agency (DTRA). Military relevance is a critical component of the Enhanced White Paper submission. Strategic oversight for the award(s) supported by this RPP will be provided by DTRA's Chemical and Biological Technologies Department (RD-CB), in its role as the Joint Science and Technology Office (JSTO) for the Chemical and Biological Defense Program (CBDP).

This RPP is focused on the development of a software prototype that will allow a medical planner to assess the residual operational risk for a mission after layering in threat risk, medical countermeasure (MCM) risk-benefit tradeoffs, and fielding risk during mission planning. The Agile Medical Countermeasure Decision Support Tool (AMDST) layering model is intended to include all MCMs for a potential threat, including FDA-approved, repurposed, and investigational drugs. One of the goals for AMDST is to make operational planners aware of MCMs in the

investigational and repurposed drug pipeline, allowing a demand signal from operations for MCM interim fielding.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing an accelerated approach to award for this RPP. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP. Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in Section 8 of the RPP. Enhanced White Papers that fail to follow the mandatory format may be eliminated from the competition (see Section 5 for more details on the Selection process). The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

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

2.2. Funding Availability and Period of Performance

Offerors are invited to propose budgets that are commensurate with the nature, scope, and complexity of the proposed research. Although the total funding amount for this effort is unspecified, FY24 funds are available for award; the USG may apply additional dollars for subsequent years and/or follow-on efforts via post award modification to any resultant award after the evaluation and acceptance of work and cost plan. Dependent on the results and deliverables, additional time may be added to the period of performance for non-competitive follow-on tasks.

MTEC expects to make a **single award** 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 36 months.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, current MTEC members are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Section 8 of this RPP). The Government will evaluate Enhanced White Papers submitted and will select those that best meet their current technology priorities using the criteria in Section 5 of this RPP. Offerors whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2 (and may be required to submit additional documentation or supplemental information such as those examples listed under Section 4.3). Notification letters will contain specific Stage 2 proposal submission requirements.

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award (RPA) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed a MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.4. Proposers Conference

MTEC 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.

2.5. 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 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 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, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants, 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.

2.6. MTEC Member Teaming

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

2.6.1 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.

2.6.2 MTEC Database Collaboration Tool

MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. The Database Collaboration Tool provides a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. 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.

2.6.3 Chat Forum

A dedicated chat forum has been established to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. The chat forum can be accessed via the "Discuss Portal" on the MTEC members-only website - https://private.mtec-sc.org/.

2.7. Offeror Eligibility

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

2.8. Cost Sharing Definition

Cost sharing is defined as the 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.).

2.9. Cost Sharing Requirements

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**. 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.

2.10. 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 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".

2.11. Intellectual Property and Data Rights

Baseline 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 contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. Due to this project's unique requirements, the Government is identifying, in this RPP, the following level of specifically-negotiated IP and Data rights required by the Government for this project. The Awardee shall grant to and/or obtain for the Government, Government Purpose Rights to all Category A and Category B Data including all documents, software, and materials developed under this award, and those developed prior to award by the Awardee or other entity, which are needed for the purposes of cybersecurity assessments, software updates, upgrades and capability insertions for future enhancements of the project deliverables (this may include but is not limited to executables, source code, algorithms, associated scripts, build procedures, automation scripts, tools, databases, libraries, test results, data sets, firmware, and training materials). The documents, software, and materials developed under this award, as well as those developed prior to award as mentioned in the preceding sentence, shall be Offeror owned, with the Government receiving Government Purpose Rights therein. Any Commercial Computer Software and/or Data needed for the purposes herein described must be delivered with a commercial license granting to the Government rights equivalent to the Government Purpose Rights described herein. The documents, software and materials produced under the Award shall not be sold back to a different Government entity as the Government is receiving Government Purpose Rights therein. All documents, materials and software supplied to the Government under this Award shall be conveyable to other government entities and third parties within the limitations of a Government Purpose Rights license as mentioned above, with no notice to or authorization from the Offeror needed. This right does not abrogate any other Government rights. For purposes of this this section (i.e., paragraph 2.11), the terms "developed" and "government purpose" shall have the same definition as utilized in DFARS 252.227-7014.

See Attachment 6 of the PPG for more detail. Note that as part of the Stage 1 of the RPP process (submission of an Enhanced White Paper), Offerors shall complete and submit Attachment 6 of the PPG (Intellectual Property and Data Rights) as an appendix to the Enhanced White Paper 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.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning May of 2024 (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.

2.13. Anticipated Enhanced White Paper Selection Notification

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

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

3 Technical Requirements

3.1. Background

The Defense Threat Reduction Agency (DTRA) Chemical and Biological Technologies Department (RD-CB), in its role as the Joint Science and Technology Office (JSTO) for the Chemical and Biological Defense Program (CBDP), manages a broad portfolio of basic and applied research and advanced technology development activities to support critical chemical and biological (CB) defense missions. Within DTRA RD-CB, the Digital Battlespace Management Division (RD-CBI) provides the warfighter with comprehensive CB data fusion and analytic capabilities to support situational awareness, decision making, and threat management.

Military medical planners require a decision support tool to enable the holistic evaluation of the residual risk to a mission from CB threats by assessing threat agent risk, alongside MCM benefits and risks as well as timely fielding risks of layered MCM strategies, including Food and Drug Administration (FDA) approved, repurposed and investigational MCMs. This concept is the basis for the AMDST.

AMDST is intended to provide a threat agnostic quantitative risk assessment framework that enables the assessment of key MCMs (vaccines, pre- and post-exposure prophylactics, and therapeutics) relevant to a potential threat, including FDA approved, repurposed, and investigational drugs to allow an operational planner to quantitatively assess an overall residual risk to a mission associated with a CB threat agent alongside benefits and safety of MCMs, and operational relevant to the threat agent.

Ongoing efforts are focused on developing the analytical framework that will power AMDST. The quantitative framework is represented by metric, and submetric scores, which are weighted and organized into a hierarchy of elements underneath three top-level risk and benefit Assessment Factors. The framework applies to selection and fielding of combinations or layered MCM plans for a mission but does not apply to administration of MCMs to individual

warfighters. One of the key outputs of the tool shall be a set of layered MCM plans for a specific mission.

Objective:

The objective of this effort is to develop a decision support software prototype [AMDST] to enable users with a range of expertise to compare operationally relevant risks and benefits of layered MCM plans. AMDST shall facilitate:

- Timely assessment and examination of various layered MCM courses of action (COAs)
- Analysis of risk-benefit tradeoffs during mission planning with CB threat potential
- Allowing a user with limited to no medical knowledge to compare COAs and, as needed, send a demand signal for specific investigational or repurposed MCMs up-the-chain of command
- Provide visualizations of residual risk scores among a set of candidate COAs for the planner to display to a decision maker for MCM planning in response to a mission.
 - Note: The scope of a COA will be limited to pre-planning, staging, and deployment of different MCMs to the battlefield in support of the mission and not on the administration of MCMs into an individual warfighter.

3.2. Solution Requirements

DTRA's RD-CBI is seeking interdisciplinary teams of performers with both medical expertise and software development experience to address the following requirements:

- 1. Develop a software application that includes a Graphical User Interface (GUI) capable of:
 - a. Supporting threat agnostic risk assessments by allowing end-users to either select standard planning options or input customized settings for various factors (e.g., MCM options, mission characteristics, threat characteristics)
 - b. Converting and integrating an existing Excel- and MATLAB-based analytical framework into an open source programming language (e.g., R, Python)
 - Automatically accessing and ingesting gold standard databases with a mechanism that provides for continuous database updates at various periodicities; databases, file formats, and their respective periodicities will be determined in coordination with DTRA
 - d. Incorporating additional, ad hoc, data streams or files, to include verification of source data
 - e. Functioning as a web-based platform via GovCloud resources/real-time feeds as well as a standalone system that includes built-in data
 - f. Ensuring user-based access is secured in accordance with DoD Development, Security, and Operations (DEVSECOPS) standards (e.g., two-factor or CAC-enabled authentication)
- 2. Prototype software is expected to support:

- Direct end-user decision making through the generation of both standard and customized reports, which will be formatted and designed in coordination with RD-CBI and end-users
- Interoperability with other systems/applications through the exchange of data and visualizations (e.g., Discovery of Medical Countermeasures Against New and Emerging threats (DOMANE), Algorithm Generator to Explore Novel Threats Leveraging the Rapid AI Platform for Innovating Data Science (AGENT-RAPIDS), Rapid Access to Products in Development (RAPID))

3. AMDST software development shall:

- a. Implement a modular design to allow for maximum flexibility in maintenance, further development, and/or integration with other systems/applications as noted above
- Follow an agile development process with incremental software deliveries and incorporation of Continuous Integration/Continuous Development (CI/CD) processes

3.3. Additional Considerations

Highly competitive proposals will address all of the objectives and requirements above and demonstrate prior successful experience in prototype development as well as foundational knowledge in current and emerging CB threats, MCMs characteristics, and medical planning. Performer teaming arrangements are encouraged. A successful prototype must be capable of developing software ingestion pipelines to automatically extract relevant medical data from disparate inter- and intra-agency database. Thus, proposals should discuss data sources and address the feasibility of developing pipelines to automatically extract relevant data into AMDST that will populate the metrics within the backend analytic algorithms powering the front-end GUI and visualizations. Further, proposals should also outline a risk management plan to address any potential technical challenges and proposed solutions in their scientific approach. The selected Member is expected to coordinate with other Government-funded contractors, at the Government sponsor's direction, to ensure successful data integration into AMDST, and incorporation of end-user feedback through participation in user engagement events and technical interchange meetings.

It is the intent that a contractual relationship with other Government-funded contractors would be executed under the MTEC OTA. Interested parties are encouraged to review the MTEC Base Agreement, which includes the overarching terms and conditions from the OTA for prototype projects between the Government and MTEC that all Research Project Awardees are expected to agree to. The MTEC Base Agreement can be found on the MTEC Website (within the Documents Library: https://www.mtec-sc.org/documents-library/) and the Members-Only website at www.mtecsc.org.

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 PoP.

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

3.5. Guidance Related to DoD-Affiliated Personnel for Participation

Compensation to DoD-affiliated personnel for participation:

Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction (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 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced 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 Offeror shall include MTEC Solicitation Number (MTEC-24-04-AMDST) in the Enhanced White Paper.

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory**. Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due date/time to clarify requirements (both administrative and technical in nature).

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

4.2. Instructions for the Preparation & Submission of the Enhanced White Paper

Offerors submitting an Enhanced White Paper 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 should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. Offerors 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 (5): Submitted via BIDS (5MB or lower per document)

- Enhanced White Paper: one Word or PDF document (Section 8 of the RPP)
- 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**: one Word or PDF document (**Attachment 5 of the PPG**) summarizing 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.
- Intellectual Property and Data Rights Assertions: one Word or PDF document (Attachment 6 of the PPG)

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page; excluding references). The following Appendices are <u>excluded</u> from the page limitation: (1) Warranties and Representations, (2) Statement of Work, (3) Current and Pending Support, and (4) Intellectual Property and Data Rights Assertions.

The Enhanced White Paper and its Appendices must be in 12-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. Enhanced White Papers and Appendices exceeding the page limitations and/or the file size specified above may not be accepted. Each document shall be uploaded to BIDS separately (see Attachment 7 of the PPG for BIDS instructions).

FOR INFORMATION ONLY: Please note a full Cost Proposal will be requested if the Enhanced White Paper is selected for funding (see Section 4.3 for additional details). Furthermore, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission <u>may</u> be requested after completion of the technical evaluation to include the following:

• **Letter(s) of Support**, as applicable, if the prototype project will require access to activeduty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix is subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided (as part of the Selection Notification described in 2.13).

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

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

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

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

See below for additional instructions. Also refer to **Addendum 1 of this RPP** for details on how the full Cost Proposals will be evaluated:

The Cost Proposal shall be submitted in two separate sections. One Word (.docx or .doc) or PDF file for **Section I: Cost Proposal Narrative** and one Excel (.xlsx or .xls) or PDF file for **Section II: Cost Proposal Formats** is required.

Offerors are encouraged to use their own cost formats such that the necessary detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC website and within the PPG are **NOT** mandatory.

Each cost proposal should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable. Refer to the MTEC PPG for additional details.

Those Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects of the Stage 2 requirements are clearly understood by both parties.

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

The cost of preparing Enhanced White Papers and Cost Proposals in response to this RPP is not allowable as a direct charge to any resulting award or any other contract. Additionally, the MTEC

Assessment Fee (see Section 2.10 of this RPP) is not allowable as a direct charge to any resulting award or any other 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 MTEC PPG.

4.6. Telecommunications and Video Surveillance

As stated in Section 6.1.2 of the MTEC PPG, 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.

5 Selection

5.1 Preliminary Screening

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. Additionally, the Government reserves the right to request additional information or eliminate Enhanced White Papers that do not meet these requirements from further consideration.

5.2 Enhanced White Paper (Stage 1) Evaluation

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above) to the Government for full evaluation. Evaluation of Enhanced 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 Enhanced 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 overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

The evaluation factors and evaluation criteria are described below in descending order of importance.

Evaluation Factors

1. Technical Feasibility

- 2. Experience and Expertise
- 3. Potential for Transition

Evaluation Factor #1 – Technical Feasibility: This factor will evaluate the relevancy, thoroughness, completeness, and feasibility of the proposed strategy for: integrating the analytic risk assessment algorithms; developing a user-friendly, customizable graphic user interface; visualizing data; generating reports; and accessing, ingesting, and authenticating data sources. The Government will consider how well the proposal defines and describes a prototype that can meet the expected attributes/capabilities and technical requirements to be set forth in this RPP. The Government may consider the SOW and estimated budget as an aspect of overall Technical Feasibility.

Evaluation Factor #2 – Experience and Expertise: This factor will evaluate the offeror's previous experience developing software applications for end-users with a range of expertise, ingesting and processing various data sources/streams, and the offeror's expertise in chemical and biological threat agents, and familiarity with medical response planning and modeling and simulation. As part of this evaluation factor, the Government will also consider the project management plan, experience of key personnel, and the ability for the technical and management team to execute the proposed SOW in an efficient and effective manner. The Government will also consider whether the proposal includes a realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

Evaluation Factor #3 – Potential for Transition: The offeror's proposal will be assessed for its potential to transition to the Government. This factor will assess how well the offeror complies with IP and data rights considerations to be fully described in this RPP, which require Government Purpose Rights (or a commercial license granting to the Government rights equivalent to the Government Purpose Rights for any Commercial Computer Software and/or Data to be described in this RPP) to all documents, software, and materials, including the source codes, algorithms, libraries and additional files required to compile and run the software, developed under this award. Additional factors evaluated in this section include interoperability with a DoD DevSecOps framework, including clear path of establishing continuous integration and continuous delivery (CI/CD) pipelines in a Software Integration Plan.

Table 1 explains the adjectival merit ratings that will be used for the Evaluation Factors.

TABLE 1 - GENERAL	ABLE 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. Proposal is not awardable.			

Please also refer to Section 5.3 for definitions of general terms used in technical evaluations.

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)

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.

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

5.3 Definition of General Terms Used in Evaluations

<u>Significant Strength</u> – 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.

<u>Strength</u> – 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.

<u>Significant Weakness</u> – A flaw that appreciably increases the risk of unsuccessful award performance.

<u>Deficiency</u> – 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.

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

<u>Sufficient</u> - The ROM estimate is within the available funding limits and considered appropriate to successfully complete the proposed project

<u>Insufficient</u> - The ROM estimate is lower than what is considered appropriate to successfully complete the proposed project

<u>Excessive</u> - 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:

- 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 Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions should be directed to the MTEC Program Director, Mr. Evan Kellinger, mtec-sc@ati.org

7 Acronyms/Abbreviations

AMDST Agile Medical Countermeasure Decision Support Tool

ATI Advanced Technology International

CB Chemical and Biological

CBDP Chemical and Biological Defense Program

CI/CD Continuous Integration and Continuous Delivery

CM Consortium Manager

CMA Consortium Member Agreement

CMC Chemistry, Manufacturing, and Controls

COA Course of Action

DCAA Defense Contract Audit Agency

DCMA Defense Contract Management Agency

DoD Department of Defense

DODI Department of Defense Instruction
DTRA Defense Threat Reduction Agency
F&A Facilities and Administrative Costs

FAQ Frequently Asked Questions
FDA Food and Drug Administration
FOIA Freedom of Information Act

FY Fiscal Year

G&A General and Administrative Expenses
Government U.S. Government, specifically the DoD

GUI Graphical User Interface

IP Intellectual Property (e.g., patents, copyrights, licensing, etc.)

JSTO Joint Science and Technology Office

MCM Medical Countermeasure
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 PDF Portable Document Format

POC Point-of-Contact

PoP Period of Performance
PPG Proposal Preparation Guide
R&D Research and Development

RD-CBI DTRA's Digital Battlespace Management Division

ROM Rough Order of Magnitude
RPA Research Project Award
RPP Request for Project Proposals

SME Subject Matter Expert SOW Statement of Work

USAMRDC U.S. Army Medical Research and Development Command

USG U.S. Government

8 Enhanced White Paper Template

Cover Page

[Name of Offeror]

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

Unique Entity ID: [UEI] CAGE code: [CAGE code]

[Title of Enhanced White Paper]

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

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:

This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium

Management Firm and the Government. If, however, an agreement is awarded as a result of, or in

connection with, the submission of this data, the MTEC Consortium Management Firm and the

Government shall have the right to duplicate, use, or disclose these data to the extent provided in the

resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the

Government's right to use the information contained in these data if they are obtained from another

source without restriction. The data subject to this restriction is (clearly identify) and contained on pages

(insert page numbers).]

[Title of Enhanced White Paper]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Describe how the proposed technology meets the needs specified in this RPP.

Scope Statement

• Define the scope of the effort and clearly state the objectives of the project.

Scientific Rationale / Preliminary Data

• Describe the scientific rationale for the project, including a brief description of previous related work data that supports the feasibility of proposed work.

Technical Approach

- Describe the design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action to address the solution requirements (Section 3.2)
- Offerors are encouraged to provide a rough order magnitude price for each task required to meet the solution requirements

Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have, if successful, in supporting the goal of the AMDST effort, to include the flexibility and customizability of the proposed solution, as new threat agent and MCM data becomes available.

Technical and Management Team

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

Resources

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

Transition to the Government

- Describe the software deliverables and computational resources required for data processing and storage envisioned to support the final vision of the proposed solution.
- Describe previous/existing partnerships with industry or the USG/DoD (including any resultant contracts/grants/awards and/or IP).

Schedule

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

Risk Identification and Mitigation

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

Rough Order Magnitude (ROM) Pricing

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

	Year 1	Year 2	Year 3	TOTAL
Labor	\$ 100,000.00	\$ 100,000.00	\$ 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)/Subcontract or(s) (subKTR)*	\$0.00	\$0.00	\$0.00	\$0.00
Gov't/Military Prtnrs / subKTR Hours*	0.0 hrs	0.0 hrs	0.0 hrs	0.0 hrs
Consultants	\$ 10,000.00	\$ 10,000.00	\$ 10,000.00	\$ 30,000.00
Consultants Hours	100.0 hrs	100.0 hrs	100.0 hrs	300.0 hrs

Material/Equipment	\$ 75,000.00	\$ 75,000		\$ 225,000.00
Other Direct Costs	\$ 1,000.00	EXAMPLE	\$ 1,000.00	\$ 3,000.00
Travel		EXAM-00.00	\$ 5,000.00	\$ 15,000.00
Indirect costs	5,200.00	\$ 48,200.00	\$ 48,200.00	\$ 144,600.00
Total Cost	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Fee (Not applicable if cost share is proposed)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Total Cost (plus Fee)	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 290,000.00	\$ 290,000.00	\$ 290,000.00	\$ 870,000.00
Total Project Cost	\$ 579,200.00	\$ 579,200.00	\$ 579,200.00	\$ 1,737,600.00

^{*}Use the rows above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

Estimate Rationale

• The Offeror must provide a **brief** rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

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

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

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

Appendix 2: Statement of Work (template provided in Attachment 4 of the PPG)

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

Appendix 3: Current and Pending Support (template provided in Attachment 5 of the PPG)

• Summarize other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request.

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

- The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government in accordance with Section 2.11 of the RPP unless otherwise asserted in the proposal and agreed to by the Government.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables/milestones. If applicable, complete the table within the referenced attachment for any items to be furnished to the Government with restrictions.

Addendum 1 – Stage 2 Evaluation Criteria

For Information Only - Stage 2 Requirement (subject to change)

Stage 2

The MTEC Consortium Manager (CM) will evaluate the cost proposed together with all supporting information for realism (as applicable, dependent upon contract type, i.e., Firm Fixed Price, Cost Reimbursable), reasonableness, and completeness as outlined below. The MTEC CM will then provide a formal assessment to the Government at which time the Government will make the final determination whether or not the negotiated project cost is fair and reasonable.

a) **Realism**. Proposals will be evaluated (for those that will result cost reimbursable type Research Project Awards) to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's technical approach and Statement of Work.

Estimates are "realistic" when they represent what the cost of the project should be for the effort to be accomplished, assuming reasonable economy and efficiency. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

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

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

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

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

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

Government Access to Information

After receipt of the cost proposal and after the CM's completion of the cost analysis summarized above, the government may perform a supplemental cost and/or price analysis of the submitted cost proposal. For purposes of this analysis, the 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 overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

Addendum 2 – Software Development Guidelines

Under the resultant award, the performer must ensure configurations and installations are designed to meet the Cybersecurity requirements set forth in <u>DoDI 8500.1</u>, <u>Incorporating Change 1</u>, <u>Effective October 7</u>, <u>2019</u> (current version). Cybersecurity implementations must be certified in accordance with <u>DoDI 8510.01</u> (current version).

Installation of software deliverables within a DTRA pre-production or software development or lab environment is contingent upon Senior Information Security Officer (SISO) review and approval of the controls used to isolate the test or evaluation instance from DTRA's operational networks and dependent upon the controls proposed, may require software code analysis.

Work conducted under this effort must be in alignment with the following DoD policies:

- DoDI 8500.1 Cybersecurity, Incorporating Change 1, 7 October 2019
- DoDI 8510.01 Risk Management Framework (RMF) for DoD Information Technology (IT),
 Incorporating Change 3, 29 December 2020
- DoD 8570.01-M Information Assurance Workforce Improvement Program, Incorporating Change 4, 10 November 2015
- Application Security and Development (ASD) Security Technical Implementation Guide (STIG) Overview Version 5, Release 1, 23 October 2020
- DoDI 8582.01 Security of Non-DoD Information Systems Processing Unclassified Nonpublic DoD Information, 9 December 2019
- DoD Developer's Guidebook for Software Assurance