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Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide / BA 3: Advanced Technology Development (ATD)</i>	R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
Total Program Element	-	184.348	197.824	238.407	-	238.407	248.071	256.357	256.706	245.793	Continuing	Continuing
EN3: <i>Enabling Investments (ATD)</i>	-	0.000	0.000	42.590	-	42.590	43.197	43.198	44.449	44.449	Continuing	Continuing
MT3: <i>Mitigate (ATD)</i>	-	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing
PT3: <i>Protect (ATD)</i>	-	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing
UN3: <i>Understand (ATD)</i>	-	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing
ET3: <i>Emerging Threats (ATD)</i>	-	0.000	6.000	0.000	-	0.000	10.000	10.000	10.000	10.000	Continuing	Continuing
CB3: <i>Chemical Biological Defense (ATD)</i>	-	26.844	26.950	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	53.794
NT3: <i>Non-Traditional Agents Defense (ATD)</i>	-	13.001	18.396	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	31.397
TM3: <i>Techbase Medical Defense (ATD)</i>	-	134.162	137.691	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	271.853
TT3: <i>Technology Transition (ATD)</i>	-	10.341	8.787	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	19.128

A. Mission Description and Budget Item Justification

This program element (PE) resources Advanced Technology Development across the Enabling Investments, Mitigate, Protect, and Understand portfolios. Chemical and Biological Defense Program (CBDP) investments provide an integrated, layered capability to enable combating weapons of mass destruction (CWMD) missions ranging from combat operations to Department of Defense (DoD) support to domestic incident prevention and response. The Projects in this PE demonstrate technologies supporting transition to advanced component development for physical capabilities which cover chemical and biological (CB) detection, situational awareness and effects modeling, and protection and hazard mitigation. FY23 funding accelerates characterization and situational awareness of emerging biothreats and accelerates delivery of improved protection from and mitigation of biothreats, including rapid repurposing of available therapeutics and development of new vaccines.

Individual Projects include:

- Enabling Investments (EN3): Demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination, including non-traditional agents. Continued efforts to enhance military operational capability, concepts of operation, and WMD elimination.
- Mitigate (MT3): Production of therapeutic candidates for bacterial, viral, and toxin threats.

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- Protect (PT3): Production of pretreatment candidates for bacterial, viral, and toxin threats.
- Understand (UN3): Demonstration of enhanced chemical detection capabilities for aerosols and non-traditional agents, expanded capabilities for biosurveillance in pathogen detection and diagnosis, produce biological diagnostic arrays and reagents and, diagnostic device platforms.
- Emerging Threats (ET3): identify and develop scientific solutions, or to modernize capabilities, that allow for a more rapid response to emerging threats.
- Chemical Biological Defense (CB3), Non-Traditional Agents (NTA) Defense (NT3), Techbase Medical Defense (TM3) and Technology Transition (TT3) are no longer active FY23 Projects due to budget restructure.

The CBDP Science and Technology (S&T) Advanced Technology Development stakeholders: The U.S. Army Combat Capabilities Development Command Chemical Biological Center (DEVCOM CBC), United States Army Medical Research Institute of Infectious Diseases (USAMRIID), United States Army Medical Research Institute of Chemical Defense (USAMRICD), United States Army Natick Soldier Systems Center, Naval Research Lab (NRL), Air Force Research Lab (AFRL), among others. The intent is to maintain strategic partnerships with the DoD Service communities for mission success across the enterprise through collaborative planning and programming maintaining budget assurance.

Work conducted under this PE will transition to and will provide risk reduction for Advanced Component Development and Prototypes (PE 0603884BP) and System Development and Demonstration (PE 0604384BP) activities.

B. Program Change Summary (\$ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	191.001	197.824	0.000	-	0.000
Current President's Budget	184.348	197.824	238.407	-	238.407
Total Adjustments	-6.653	0.000	238.407	-	238.407
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	-			
• Congressional Directed Transfers	0.000	-			
• Reprogrammings	-3.110	-			
• SBIR/STTR Transfer	-3.543	-			
• Other Adjustments	0.000	-	238.407	-	238.407

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: CB3: *Chemical Biological Defense (ATD)*

	FY 2021	FY 2022

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Congressional Add Details (\$ in Millions, and Includes General Reductions)

Congressional Add: *High Air Flow ChemBio Filtration System Enhancement*

Congressional Add Subtotals for Project: CB3

Congressional Add Totals for all Projects

	FY 2021	FY 2022
	3.000	-
	3.000	-
	3.000	-

Change Summary Explanation

Funding: FY 2021 (-\$3.110 Million): Below threshold reprogramming to increase advanced development programs for implementation of common CBRN integrated systems architecture within the CBRN Integrated Early Warning (CBRN IEW) program, Joint Nuclear Biological Chemical Radiological System (JNBCRS) 1 CBRN sensor development and integration, Man Portable Diagnostic System (MPDS) product development, and RDT&E Management Support efforts.

FY 2021 (-\$3.543 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY 2021 (+\$3.000 Million): Congressional Add for High Air Flow Chemical Biological (CB) Filtration System Enhancement is reflected in the Current President's Budget amount.

FY 2023: Funding increase reflects the fact that the FY 2022 President's Budget request did not include out-year funding. Funding includes specific increases for enhanced biodefense and pandemic preparedness investments (+\$49.581 Million).

Schedule: N/A

Technical: N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) EN3 / Enabling Investments (ATD)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
EN3: <i>Enabling Investments (ATD)</i>	-	0.000	0.000	42.590	-	42.590	43.197	43.198	44.449	44.449	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The Enabling Investments Advanced Technology Development (ATD) Project focuses on early and continued involvement of the Warfighter in the technology development process and has implemented a user community engagement process to align science and technology (S&T) activities with operational needs and ensure functional design. This process begins with the identification of an innovative technology concept, continues through the assessment of the prototype, and ends at the operational and utility demonstrations to enhance transition to an advanced developer. Enabling efforts in this area support dedicated infrastructure capabilities, demonstrations, and overarching development support functions as portfolio enablers responding to emerging threats.

Thrust Areas included in this Project are:

- (1) Advanced Technology Demonstration
- (2) Technology Concept
- (3) User Assessments
- (4) Battlefield Readiness
- (5) Emerging Threats
- (6) Diagnostic Building Blocks
- (7) Medical Countermeasures Initiative

Advanced Technology Demonstration: Facilitates Warfighters and other operational stakeholders participation in field demonstrations that evaluate integrated prototype systems in high fidelity and realistic operating environments. ATDs provide feedback to developers and help shape S&T innovative solutions for employment across the spectrum of Joint Force actions in the chemical, biological, radiological, and nuclear (CBRN) defense arena. Advanced Technology Demonstration outcomes mitigate transition risk by demonstrating operational utility and enhancing transition to an identified Chemical and Biological Defense Program (CBDP) program of record.

Technology Concept: Validates technology requirements and scopes future S&T programs with the User community early in technology development process. Results from these experiments shape operating concepts, doctrine, and materiel systems requirements for the future Joint Force and informs the utility of emerging technologies for subsequent portfolio investment decisions. Technology Concept outcomes explore new concepts of employment for emerging capabilities to shift the current operational paradigm.

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User Assessments: Provides opportunities for early Warfighter input into the form, fit and function of maturing S&T prototypes and technologies. Early user assessments can validate employment concepts, and serve as baselines for future Advanced Technology Demonstration efforts. User Assessment outcomes explore how to push the state of future technology through system mockup and early prototyping.

Battlefield Readiness: Provides innovative capabilities to the Warfighter that increase the speed of relevancy, enhances troop preparedness, aids with triage support, and provides diagnosis at lower roles of care. Develops field forward medical diagnostics to provide multiplexed detection of biological and toxin threats and leverages immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.

Emerging Threats: Invests in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure, to greatly advance efficacy rates and turnaround time for Warfighter wellness. Efforts focus on better preparing for surprise by developing diagnostic systems that leverage novel approaches to characterize pathogens or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample.

Diagnostic Building Blocks: Develops foundational capabilities for the entire diagnostics portfolio; invests in innovative, cutting-edge technologies to improve the development pipeline for diagnostics; and exploits areas in artificial intelligence synthetic biology and machine learning to develop novel and rapid diagnostic tests for utilization. Efforts accelerate assay development timelines and optimize test parameters by leveraging novel concepts and tools that readily allow a pivot to assay development for emerging threats.

Medical Countermeasures Initiative: Advances medical capabilities to support CB Incident Preparedness Response (CBIPR). Efforts focus on Advanced Development and Manufacturing capability development through the Bacterial Expression, CRM Conjugate, Marburg vesicular stomatitis vaccine (VSV MARV), deoxyribonucleic acid (DNA) Vaccine and Advanced Development and Manufacturing of Antibody Technology (ADAMANT) Insertions projects; laboratory sustainment for the Animal Model/ Response Capability; genomics; and chemical warfare agent (CWA) Diagnostics; and other medical countermeasure development through the In-vitro Affinity Diagnostic System and antimicrobial susceptibility projects.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Title: 1) Advanced Technology Demonstration</p> <p>Description: Advanced Technology Demonstrations (ATDs) facilitate Warfighters and other operational stakeholders' participation in field demonstrations that evaluate integrated technologies or prototype systems with demonstrated technical performance in high fidelity and realistic operating environments. Building on the Technology Concepts and User Assessments thrust areas conducted earlier in the technology maturation process, feedback from the Warfighters during ATDs ensures that these technologies are operationally relevant, value added, and can be matured and potentially transitioned in a timely and effective manner to transition partners for advanced development and employment across the spectrum of Joint Force actions in a chemical, biological, radiological, and nuclear (CBRN) defense Environment. ATD outcomes area designed to enhance transition of cutting edge CBRN technologies and mitigate transition risk by demonstrating operational utility and initial Tactics, Techniques, and Procedures (TTPs).</p>	-	-	6.195

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>FY 2023 Plans: - Continue planning and executing ATD. ATD will demonstrate integrated, innovative combating weapons of mass destruction (CWMD) technologies with the Warfighter for feedback to optimize and accelerate the maturation and delivery of needed capability to the end user; help focus Chemical and Biological Defense Program (CBDP) community engagement (e.g. CBRN Support to Command and Control (CSC2) Capability Development Packages (CDP)), building transition criteria for advanced development and fielding; inform the Warfighter on the future operating environment, driving development of concept of operation (CONOPS) and TTPs, and building out the entire Doctrine, Organization, Training, Materiel, Leadership, Personnel, Facilities, and Policy (DOTmLPF-P) capability requirements spectrum.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$5.640 Million) remains in TT3. Increase due to change in program/project technical parameters.</p>			
<p>Title: 2) Technology Concept</p> <p>Description: Initiatives to validate technology requirements and scope future S&T programs with Warfighter stakeholders, including Combat Developers and Service representatives. Results from these experiments shape Operating Concepts, doctrine, and materiel systems requirements for the future Joint Force and inform technology developers about potential Warfighter utility of emerging technologies and technology concepts for subsequent portfolio investment. Activities in this area focus on Surveys, User Groups, Table Top Exercises (TTXs), and practical demonstration or User feedback workshops to develop Use Cases, desired operational capabilities, key attributes and explore Concepts of Employment to assess feasibility/utility of emerging technologies.</p> <p>FY 2023 Plans: - Conduct 4-6 technology concept studies, workshops or Focus Groups including the continuation of distributed sensing and mitigation techniques. Additional technology concepts will be identified within this timeframe based upon technology discovery, maturity, and application to Warfighter needs.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.296 Million) remains in TT3.</p>	-	-	1.296
<p>Title: 3) User Assessment</p> <p>Description: User Assessments examine maturing technologies and provide opportunities for early Warfighter input into the form, fit, and function of maturing S&T prototypes and technologies; and as appropriate, assess them within a simulated operational environment. The assessments serve as baselines for future ATD programs, and drive S&T gap analysis for key customers and partners. User assessments are characterized by TTXs, Early User Assessments, Technical demonstrations and field</p>	-	-	1.851

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>experiments that provide candid feedback focused on applicability, utility and recommended improvements while exploring system limitations, vulnerabilities and technology tradeoff analyses of innovative technologies in a non-attributional environment.</p> <p>FY 2023 Plans: - Continue the annual CB Operational Analysis (CBOA) event.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.851 Million) remains in TT3.</p>				
<p>Title: 4) Battlefield Readiness</p> <p>Description: Provide innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care. Develop field forward medical diagnostics that allow for multiplexed detection of biological and toxin threats. Leverage immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.</p> <p>FY 2023 Plans: - Continue the development of additional panels for infectious disease diagnostic tests on the immunological diagnostic platform.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Program/project funding transferred from another funding line. FY22 funding (\$4.400 Million) remains in TM3. Increase due to change in program/project technical parameters.</p>		-	-	5.094
<p>Title: 5) Emerging Threats</p> <p>Description: Advance the diagnosis of emerging and/or low prevalence but high threat biological agents leveraging novel technologies. Develop threat agnostic tests based on host biomarkers that identify known or emerging bacterial or viral infections. Characterize markers for antibiotic resistance or susceptibility to identify challenging threats and inform treatment decisions. Improve capabilities to identify diverse biological agents that are not well characterized using molecular or immunodiagnostic approaches.</p> <p>FY 2023 Plans: - Initiate efforts that establish multiple capabilities for Warfighters to combat new and emerging threats to include identifying novel platforms that are capable of identifying broad classes of threat agents in complex matrices.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	2.264

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Program/project funding transferred from another funding line. FY22 funding (\$3.851 Million) remains in TM3. Decrease due to change in technical parameter.				
<p>Title: 6) Diagnostic Building Blocks</p> <p>Description: The Diagnostic Building Blocks thrust area lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue novel efforts in Artificial Intelligence (AI) and ML for designing assays with high specificity against a broader range of CB agents to enable an agile response to emerging threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Program/project funding transferred from another funding line. FY22 funding (\$2.751 Million) remains in TM3. Increase due to change in program/project technical parameters.</p>		-	-	3.962
<p>Title: 7) Medical Countermeasures Initiative</p> <p>Description: The Chem Bio Incident Preparedness and Response-Medical Countermeasures Initiative (CBIPR-MCMI) will integrate advances in regulatory science and flexible manufacturing technologies and processes; and develop animal models and drug discovery and evaluation platforms as enablers of the advanced development of CBDP medical countermeasure products. These initiatives will lead to the establishment of multi-use platforms and animal models that can be leveraged during a CBRN response to accelerate medical product development and/or regulatory approval as well as reduce overall development costs.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete preclinical studies for Marburg vesicular stomatitis vaccine (VSV) for initiation into a Phase 1 clinical trial. - Continue Burkholderia outer membrane vesicle (OMV) vaccine manufacturing to support Phase 1 clinical trial. - Conduct good laboratory practice (GLP) toxicology on Burkholderia OMV vaccine prior to entry into Phase 1 clinical trial. - Initiate good manufacturing practice (GMP) manufacturing of Francisella tularensis (FnIlgID) vaccine to support Phase 1 clinical trial. - Prepare for surprise by establishing drug discovery and evaluation platform capability that can be leveraged during a CBRN response. - Continue to develop and advance animal models to accelerate medical countermeasure (MCM) delivery and the capacity to respond to emerging biological threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	21.928

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$21.602M) remains in TM3.			
Accomplishments/Planned Programs Subtotals	-	-	42.590

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023	FY 2023	FY 2023	FY 2024	FY 2025	FY 2026	FY 2027	Cost To	Total Cost
• EN4: <i>Enabling Investments (ACD&P)</i>	0.000	0.000	8.781	-	8.781	9.172	9.179	9.392	9.440	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
MT3: <i>Mitigate (ATD)</i>	-	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The Mitigate Advanced Technology Development (ATD) Project provides the Joint Force the ability to preserve combat power by mitigating exposure to chemical and biological (CB) hazards and restoring combat readiness of critical personnel and platforms.

Thrust Areas included in this Project are:

- (1) Enhanced Survivability Coatings
- (2) Equipment Decontamination
- (3) Multifunctional Materials for Protection
- (4) Personnel Decontamination
- (5) Biological Warfare Defense Therapeutics
- (6) Discovery of Medical Countermeasures Against New and Emerging (DOMANE)
- (7) Nerve Agent Prophylaxis/Pretreatments
- (8) Pharmaceutical Based Agents (PBAs)
- (9) Reactivators of Acetylcholinesterase as Therapeutics (ReACT)

Enhanced Survivability Coatings: Addresses military equipment coating ease of decontamination and resistance to chemical agent penetration. Projects will develop temporary coatings that resist chemical agent absorption and are quickly decontaminated in the field and allow the rapid regeneration of combat power.

Equipment Decontamination: Develops decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enables unit-level decontamination with rapid unmasking; reduces logistic needs, enables rapid sorting of clean from dirty to return high-value equipment to normal use, and develops improved realistic test methods. Efforts address the capability to decontaminate personal equipment. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Multifunctional Materials for Protection: Discovers, develops and integrates novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants that reactively decontaminate chemical warfare agents.

Personnel Decontamination: Develops decontaminants with lower lifecycle costs and storage constraints and determine of time, efficacy and logistics burdens to Warfighters for mass casualty decontamination, including possible substitutions for current approved personnel decontamination formulations.

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Biological Warfare Defense Therapeutics: Develops broad-spectrum bacterial, toxin and viral therapeutics, and label expansion (repurposing) of medical countermeasures that are Food and Drug Administration (FDA) approved or in advanced stages of clinical development. These efforts are coordinated with Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA), and across the interagency and Department, to leverage public and force/defense health related investments made to minimize risk and speed approval of novel antibiotic countermeasures. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Discovery of Medical Countermeasures Against New and Emerging (DOMANE): Provides innovative and rapid medical countermeasures (MCMs) development capabilities that reduce developmental risks, cost and schedule associated with MCM fielding, and afford protection against and allow the Joint Force to rapidly respond to traditional, new and emerging biological warfare threat exposures to allow freedom of action. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Nerve Agent Prophylaxis/Pretreatments: Develops and transitions novel products and information to address current and emerging chemical threats to protect the lives and effectiveness of Warfighters, thus maintaining force strength and force capability. FY23 focuses on obtaining the first prophylactic MCMs designed to prevent severe morbidity and mortality upon exposure to nerve agents without the need for additional individual physical protective equipment.

Pharmaceutical Based Agents (PBA): Assesses candidate MCMs and transitioning them to partner US Government entities for development into fieldable drug products. Activities advancing therapeutic drugs for protection against opioid agents and developing MCMs to treat non-opioid sedatives in preparation for Phase 1 or other relevant clinical trials.

Reactivators of Acetylcholinesterase as Therapeutics (ReACT): Develops broad-spectrum, centrally-acting acetylcholinesterase reactivators that increase survival, reduce morbidity, and decrease neurological damage.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Title: 1) Multifunctional Materials for Protection</p> <p>Description: This effort will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants and coatings.</p> <p>FY 2023 Plans: - Develop and characterize novel reactive/catalytic materials that decontaminate chemical and biological (CB) threats and integrate materials into next generation decontaminants and coatings.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	-	-	0.189

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding remains in CB3.				
<p>Title: 2) Enhanced Survivability Coatings</p> <p>Description: This effort seeks to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to characterize bio-inspired surface treatments for equipment coatings to repel agents of interest from current military equipment coatings. - Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays. - Advance thin repellent film coating systems from fundamental research to applied research test and evaluation. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>		-	-	0.051
<p>Title: 3) Equipment Decontamination</p> <p>Description: This effort seeks to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Transition methodology for testing for effective decontamination of complex surfaces and real-world systems to the Service Equipment Decontamination Systems (SEDS) or Tactical Contamination Mitigation Systems (TCMS) programs of record. - Finish development and demonstration of an autonomous decontamination platform to reduce troop-to-task burden of operational decontamination. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in TM3. Decrease due to change in program/project technical parameters.</p>		-	-	0.951
Title: 4) Equipment Decontamination - Enhanced Biodefense (ENBD)		-	-	6.000

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) MT3 / Mitigate (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Description: This effort will focus on Improved Decontamination and Disinfectant Options. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop and demonstrate biological disinfection guidelines, procedures, and Concepts of Operations (CONOPs) for Department of Defense (DoD) facility and large-platform interiors, including development of directed energy disinfection methods including plasma and ultraviolet germicidal irradiation. - Complete comparative laboratory study of Biosafety Level (BSL)-1 surrogate and BSL-2 human coronavirus ultraviolet (UV) disinfection to support field demonstrations. - Develop biological agent disclosure sprays for sensitive, specific biological contamination mapping on surfaces to guide and reduce logistics of decontamination. Explore solution concepts through research, development, and demonstration of one or more functional prototype technologies in a phased approach for a biological agent disclosure spray. - Demonstrate a proof of concept demonstrating specific recognition and binding of the targeted biological warfare agent of interest. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>			
<p>Title: 5) Personnel Decontamination</p> <p>Description: This effort develops decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to Warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a chemical warfare agent (CWA) exposure by identifying S&T gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop and use laboratory and animal models to assess physical removal technologies for potential replacement of Reactive Skin Decontamination Lotion (RSDL). 	-	-	0.869

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) MT3 / Mitigate (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>- Continue to integrate new dry decontamination into a mitt form factor and determine S&T challenges within process and procedure improvements. This includes investigation of Food and Drug Administration (FDA) requirements for approval of technology as a medical device.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.024 Million) remains in CB3. Decrease due to change in program/project technical parameters.</p>			
<p>Title: 6) Biological Warfare Defense Therapeutics</p> <p>Description: This effort focuses on Micro physiological Systems and Small Molecule Library and S&T Host Response Study. Funds biomedical research to include the preclinical development of therapeutic countermeasures against known and emerging biological warfare (BW) threats for which FDA-approved therapeutics are limited or lacking. BW defense therapeutics mitigate and reverse the effects of known and emerging biological warfare threats in symptomatic warfighters diagnosed with BW disease. They are the last line of defense against BW threats and are critical to returning symptomatic warfighters to service. Biomedical research is focused on preclinical evaluation (e.g., in large animal models) of broad-spectrum therapeutic candidates that target viruses, bacteria or toxins directly, enhance the host response (e.g., by modulating the immune system) and/or relieve BW disease symptoms. Broad-spectrum therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional non-clinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP), and can be accelerated for use against emerging infectious diseases during an outbreak. Preclinical evaluation of novel small molecules (chemically synthesized), novel biologic molecules (isolated from natural sources), drug and drug/ vaccine combinations (aka layered defense), and repurposing of drugs approved by the FDA or in clinical development for other indications, are included in this research. Refinement of appropriate animal models in which to evaluate therapeutic candidates is also included. Projects leverage interagency and commercial sector investments to accelerate development and reduce costs.</p> <p>FY 2023 Plans: Bacterial: - Continue efforts to identify and advance bacterial therapeutic candidates, with a focus on non-traditional candidates. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP) or transition to an advanced developer. - Continue to partner with interagency, international and industry partners to fund nonclinical BW therapeutic efficacy studies for therapeutic candidates already in advanced development for public and force health indications. - Continue to execute proof of concept efficacy studies for antibiotic therapy in combination with prophylaxis or complimentary treatments (layered medical defense). Advance layered combinations toward proof of concept in non-human primate (NHP) models.</p>	-	-	29.439

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) MT3 / Mitigate (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Viral:</p> <ul style="list-style-type: none"> - Continue efforts to identify and advance viral therapeutic candidates against new and existing BW viral threats, including direct acting, broad-spectrum anti-virals and monoclonal antibodies. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP) or transition to an advanced developer. - Continue proof of concept viral therapeutic efficacy studies for combinations of therapeutics including, small molecule, monoclonal antibody and host-directed therapeutics. <p>Toxins:</p> <ul style="list-style-type: none"> - Continue to evaluate efficacy of repurposed drug for treatment of botulinum neurotoxin (BoNT) A intoxication in NHP animal model. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in TM3. Starting in FY23, all Bacterial/Viral/Toxin Therapeutics bullets will be consolidated to new single bullet title Biological Warfare Defense Therapeutics.</p>			
<p>Title: 7) Biological Warfare Defense Therapeutics - Enhanced Biodefense (ENBD)</p> <p>Description: This effort focuses on Micro physiological Systems & Small Molecule Library & S&T Host Response Study. Activities include expediting a response to emerging threats by assessing broad-spectrum efficacy of approved drugs against biological threats (i.e., drug repurposing), advancing repurposed drugs against biological threats for FDA approval; developing tools (e.g., small molecule libraries) to expedite discovery and development of therapeutic candidates in response to an emerging threat; and, identifying and developing technologies that target host response to disease caused by biological threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate and accelerate projects to repurpose broad-spectrum drugs against viral, bacterial and toxin threats. - Initiate and continue projects to create and sustain curated, searchable databases of molecules with toxicity, drug development and efficacy data for use in a response to emerging biological threats. - Initiate development of host-targeted technologies that can be used to stop progression of disease caused by viral threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>	-	-	23.000
<p>Title: 8) Discovery of Medical Countermeasures Against New and Emerging (DOMANE)</p>	-	-	4.000

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) MT3 / Mitigate (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Description: A capability to rapidly identify both pathogen and host based targets for novel threats and find drugs for those targets coupled to a streamlined process for rapid MCM development.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continued development of prototype capability that forecasts pathogenicity or toxicity of biological threats. - Continued development of prototype capability for high-throughput screening to produce high resolution target and MCM identification. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in TM3.</p>				
<p>Title: 9) Discovery of Medical Countermeasures Against New and Emerging (DOMANE) - Enhanced Biodefense (ENBD)</p> <p>Description: This effort focuses on Repurposing Existing Therapeutics. It supports DOMANE thrusts like Pathogenesis and Toxicity forecasting using Multi-Organoid Systems PATMOS (PATMOS) prototype develops an advanced-artificial intelligence (AI) assisted multi-organoid system capable of forecasting pathogenesis of viral threats and toxicity of biotoxin threats as well as DOMANE thrusts like Medical Countermeasure Finder (MEDFIND) to a prototype that provides flexible advanced AI-assisted system capable of harnessing repurposed drugs and generate effective therapeutic intervention strategies against viral and biotoxin threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Prototype development PATMOS platform for high resolution forecasting of pathogenesis that occurs during interaction of a biological threat. - Prototype initiation for MEDFIND platform to identify repurposed drugs using AI and Machine Learning (ML). <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	12.000
<p>Title: 10) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter non-traditional agents (NTAs) and emerging chemical threats to protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability. Successful prophylactics will rapidly detoxify a broad spectrum of compounds of interest (COIs).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Submit investigational new drug (IND) submission to the FDA for organophosphorus nerve agents (OPNA) catalytic scavenger enzymes. 		-	-	1.174

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Complete Good Laboratory Practice (GLP) pharmacokinetics, immunogenicity and efficacy of catalytic scavenger enzyme lead candidates in small animals. - Complete enzyme current Good Manufacturing Practice (cGMP) manufacturing scale-up. - Complete formulation efforts. - Complete enzyme non-cGMP manufacturing scale-up. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in TM3.</p>				
<p>Title: 11) Pharmaceutical Based Agents (PBAs)</p> <p>Description: Focuses on therapeutic and proactive strategies to effectively minimize injuries and/or death resulting from exposure to PBAs. This will allow the Warfighter to maintain operational capacity in a chemically contested battlefield scenario. This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for FDA licensure or to identify previously licensed products for new uses in the treatment and pretreatment against chemical warfare injury.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development of Rapid Opioid Countermeasure System (ROCS) higher concentration Naloxone formulation for use in a multiuse vial format through New Drug Application (NDA) by FDA. - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. - Assess operational feasibility of employing FDA approved opioid antagonist MCM to provide extended duration of protection. - Continue development of novel therapeutic products to mitigate Opioid-Induced Respiratory Depression (OIRD) to reduce lethality in CWA exposed Warfighters - Continue studies to assess safety, efficacy, and tolerance of COTS products and dosages for opioid based PBA exposure. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.065 Million) remains in TM3. Decrease due to change in program/project technical parameters.</p>		-	-	3.185
<p>Title: 12) Reactivators of AChE as Therapeutics (ReACT)</p> <p>Description: The Warfighter requires rapid acting MCMs to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation.</p>		-	-	3.618

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Efforts in this area are focused on formulation development and pre-clinical studies for potential candidates that will ultimately be submitted for FDA licensure or previously licensed products for new uses in the treatment of chemical warfare casualties.			
<i>FY 2023 Plans:</i> - Continue to advance pre-clinical development of lead therapeutic candidates. - Continue formulation efforts and scale up manufacturing for lead therapeutic candidates. - Initiate GLP toxicology and long-term stability studies for lead therapeutic candidates.			
<i>FY 2022 to FY 2023 Increase/Decrease Statement:</i> Funding transferred from another Project due to budget restructure. FY22 funding (\$6.649 Million) remains in TM3. Decrease due to change in program/project technical parameters.			
Accomplishments/Planned Programs Subtotals	-	-	84.476

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• MT4: Mitigate (ACD&P)	0.000	0.000	20.986	-	20.986	13.556	12.702	20.846	18.167	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) PT3 / Protect (ATD)
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
PT3: <i>Protect (ATD)</i>	-	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The Protect Advanced Technology Development (ATD) Project enhances mission performance while providing effective protection against current and emerging chemical and biological (CB) threats, enables Joint Force lethality by protecting Warfighters against adverse effects of CB hazards, and fields protection capabilities against engineered biological agents, opioids and other Pharmaceutical Based Agents (PBAs), and Fourth Generation Agents (FGAs).

Thrust Areas included in this Project are:

- (1) Air Purification Enhancements
- (2) All-Hazards & Respiratory Protection
- (3) Multifunctional Materials for Protection
- (4) Enhanced Survivability Coatings
- (5) Dynamic Multifunctional Materials for Second Skin
- (6) Bacterial Prophylaxis
- (7) Broad Spectrum
- (8) Toxin Prophylaxis
- (9) Viral Prophylaxis

Air Purification Enhancements: Focuses on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection. Efforts optimize and extend filter life to save costs while maintaining or improving protection and improving integration of collective protection into developmental Service major combat platforms. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

All-Hazards & Respiratory Protection: Develops next generation general purpose mask that unencumbers the Warfighter and integrates with existing system technology, completes work on the Tactical All Hazards Ensemble to support special purpose units, and supports modernization efforts to insert new technologies into current respirator efforts that protect against the full spectrum of threats in support the range of military operations, to include scalable protection. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Multifunctional Materials for Protection: Efforts utilize a combination of basic and applied research to discover and develop a pipeline for the next generation materials, technologies, self-regenerating protective garments, decontaminants, and filter materials that react with chemical agents to actively decontaminate on demand and regenerate protective capacity for unencumbering the warfighter.

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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Enhanced Survivability Coatings: Efforts address materiel surface ease of decontamination and resistance to chemical agent penetration. Projects will develop temporary coatings that resist chemical agent absorption and are quickly decontaminated in the field and allow the rapid regeneration of combat power.

Dynamic Multifunctional Materials for Second Skin: Utilizes responsive technologies to provide chemical biological protective suits that adapt to the threat and environment by synthesizing scaled samples for manufacturing which exhibit materials properties that reduce thermal burden and integrate with current combat garments.

Bacterial Prophylaxis: Provides the Warfighter protection against biothreat agents through the pre-exposure administration of prophylactics against known bacterial threats of interest and emerging infectious threats. Near-term efforts include prophylaxis against agents on the tradition BW threat list followed by efforts to discover and develop advanced protectants against novel targets for the traditional threats and emerging biological warfare (BW) threats.

Broad Spectrum: Discovers and develops broadly protective strategies and nontraditional approaches against new and emerging threats followed by efforts to discover and develop broad-based strategies that address multiple serotypes/toxin classes/mechanisms of intoxication.

Toxin Prophylaxis: Provides the Warfighter protection through the pre-exposure administration of prophylactics against known toxin threats of interest and emerging infectious threats.

Viral Prophylaxis: Provides the Warfighter protection through the pre-exposure administration of prophylactics against known viral threats of interest and emerging infectious threats. The manufacturing processes for platform technologies will be adapted to maximize flexibility, increase stability, shelf life, and expand storage conditions. Efforts will also be adapted to maximize delivery flexibility through modifying delivery routes, which will allow for dose and reagent sparing.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
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Title: 1) Air Purification Enhancements - Enhanced Biodefense (ENBD)	-	-	2.000
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Description: This effort will focus on Improved Personal Protection. Existing Collective Protection (CP) systems have high life cycle costs driven by maintenance and limited service life. Science and Technology (S&T) efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.

FY 2023 Plans:

- Develop low cost, continuous-operation collective protection engineering standards and guidelines for temporary, rapid enhancement of unprotected Department of Defense (DoD) facilities during pandemic or biological warfare agent release.
- Demonstrate and validate concepts for layered protection to mitigate the biological contamination risk with passive systems for applique and facility design features.

FY 2022 to FY 2023 Increase/Decrease Statement:

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Additional investment in enhanced biodefense and pandemic preparedness.				
<p>Title: 2) All-Hazards & Respiratory Protection</p> <p>Description: This effort improves CB agent protection while maintaining Warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit Self-Contained Breathing Apparatus.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to evaluate and assess systems that provide CB respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Transition operationally-relevant respirator fit testing system to Modernization Individual Protection program of record. - Transition specification for anti-fog lenses in respirators as a Ground Mask modification work order. - Continue to design and test prototypes for a low-encumbrance, next generation protective mask. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$0.814 Million) remains in CB3. Increase due to change in program/project technical parameters.</p>		-	-	1.345
<p>Title: 3) All-Hazards & Respiratory Protection - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Expedient Isolation/Collective Protection. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit Self-Contained Breathing Apparatus.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop low cost, low burden, antimicrobial respiratory and ocular for operations specifically in a biologically contaminated environment. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	1.000
<p>Title: 4) Multifunctional Materials for Protection</p> <p>Description: This effort discovers, develops, and integrates novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure</p>		-	-	0.756

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials (derived from Applied Research efforts) into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Advance next generation materials to design reactive, regenerative protective garments with longer service life and lower thermal burden. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. F22 funding remains in CB3.</p>			
<p>Title: 5) Lightweight Protective Garments - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Expedient Isolation/Collective Protection. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop low cost, low burden, antimicrobial respiratory and ocular for operations specifically in a biologically contaminated environment. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>	-	-	1.000
<p>Title: 6) Dynamic Multifunction Materials for Second Skin</p> <p>Description: This effort utilizes responsive technologies to provide CB protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development and testing of protective garment materials that respond to the presence of chemical agents to increase Warfighter protection. 	-	-	1.170

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) PT3 / Protect (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
- Begin integration of responsive systems into protective suit paradigms for whole system testing.			
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.379 Million) remains in CB3. Decrease due to advancement of program/project research from Applied Research.			
Title: 7) Enhanced Survivability Coatings Description: This effort seeks to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military materiel to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return materiel to mission operations level. FY 2023 Plans: - Continue to characterize bio-inspired surface treatments for materiel coatings to repel agents of interest from materiel surfaces. - Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays. - Advance thin repellent film coating systems from fundamental research to applied research test and evaluation. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$0.345 Million) remains in CB3.	-	-	0.416
Title: 8) Biological Warfare Defense Prophylaxis Description: The ultimate protection of the Warfighter is by pretreating the Warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the Warfighter to work in a less restrictive environment, absent of any personal protective equipment allowing operation at peak performance. Investments support de-risking of candidates for transition into advanced development and includes: manufacturing process development, pre-clinical studies for lead candidates to allow initiation of clinical work, regulatory science to support clinical initiation, animal model development for Food and Drug Administration (FDA) animal rule licensure, and Phase 1 clinical trials. Candidates transition into advanced development once the Phase 1 clinical trial is complete. FY 2023 Plans: Bacterial: - Complete Good Manufacturing Practices (GMP) manufacturing for Tularemia prophylaxis with the ClpB vaccine and Burkholderia CPS conjugate vaccine for advancement to clinical Phase 1. - Complete manufacturing and nonclinical development of adjuvanted plague vaccine for advancement to clinical Phase 1. - Initiate toxicology studies of adjuvanted plague vaccine in support of clinical Phase 1.	-	-	27.632

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) PT3 / Protect (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Continue non-clinical safety and efficacy studies of monoclonal antibody cocktail against plague and Burkholderia. - Continue layered defense studies for bacterial threats to test vaccines, antibody therapies and antibiotics in combination. - Continue non-clinical safety and efficacy studies on a live attenuated plague vaccine candidate for advancement to clinical Phase 1. - Initiate manufacturing of anthrax CPS conjugate vaccine candidate for advancement to clinical Phase 1. - Complete melioidosis human seroprevalence study in support of vaccine licensure. - Complete assay development in support of clinical Phase 1 for complex vaccines. <p>Viral:</p> <ul style="list-style-type: none"> - Complete cGMP manufacture of deoxyribonucleic acid (DNA) Vaccine for the upcoming phase 1 clinical trial as well as pivotal nonclinical studies. - Continue cGMP manufacture of rVSV Marburg virus vaccine to support pivotal animal studies and upcoming phase 1 clinical trial. - Complete investigation into correlates of protection for Marburg virus survivors to support pivotal animal studies. - Continue correlates of protection studies for alphavirus vaccine animal models. - Continue evaluation and mitigation studies of Filovirus aerosol pathology. - Continue development of rVSV Marburg vaccine in animal models to support investigational new drug (IND) submission. - Complete IND package for DNA vaccine for Venezuelan Equine Encephalitis Virus for upcoming phase 1 clinical trial. - Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines - Continue assay qualification and validation for Marburg virus, and alphavirus vaccines. <p>Broad Spectrum:</p> <ul style="list-style-type: none"> - Continue development of the multivalent Nanolipoprotein vaccine against multiple bacterial agents. - Continue non-clinical safety and efficacy studies with the broad spectrum NLP vaccine for advancement to clinical Phase 1. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$34.160 Million) remains in TM3. Decrease due to change in program/project technical parameters. Starting in FY23, all Bacterial/Viral/Toxin Therapeutics bullets will be consolidated to new single bullet title Biological Warfare Defense Therapeutics.</p>			
Accomplishments/Planned Programs Subtotals	-	-	35.319

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) PT3 / Protect (ATD)
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• PT4: <i>Protect (ACD&P)</i>	0.000	0.000	203.689	-	203.689	183.220	139.375	113.754	105.176	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
UN3: <i>Understand (ATD)</i>	-	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The Understand Advanced Technology Development (ATD) Project supports freedom of maneuver and informs commanders' decisions by predicting, locating, identifying, analyzing, and warning of chemical and biological (CB) hazards.

Thrust Areas included in this Project are

- (1) Material Contamination Mitigation
- (2) Chemical Diagnostics
- (3) Distributed CB Reconnaissance
- (4) Chemical, Biological, Radiological, and Nuclear (CBRN) Battlespace Surveillance, Alerting & Response
- (5) Diagnostic Building Blocks
- (6) Emerging Threats
- (7) Battlefield Readiness
- (8) CBRN Decision Aids
- (9) CBRN Situational Awareness
- (10) Enhanced and Emerging Biothreat Sensing
- (11) Technical Surprise
- (12) Clinical Evaluation

Material Contamination Mitigation: Provides the capability to rapidly return to the level of lethality and operational tempo prior to CBRN exposure by mitigating contamination on equipment, vehicles, ships, and facilities; sensitive equipment, and hazardous waste to significantly ease burdens of decontamination and increase efficiency of decontamination process. Efforts within this thrust seek to improve contamination mitigation logistics/cost reduction, effectiveness, compatibility/safety, and environmental compatibility.

Chemical Diagnostics: Provides innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum and enhance force protection by investing in diagnostics for exposure to traditional and nontraditional chemical warfare agents (CWAs), including pharmaceutical based agents. Efforts include coordinating with Threat Agent Science and the Intelligence Community and to understand the chemical threat space.

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<p>Distributed CB Reconnaissance: Enhances early warning and situational awareness of biological threats while reducing potential Warfighter exposure using distributed biological reconnaissance tools to include low cost point sensors and sensing/collection systems for unmanned platforms. Efforts include developing threat sensing and sampling payloads for manned and unmanned aerial and ground platforms to enhance early warning and situational awareness of biological threats.</p> <p>CBRN Battlespace Surveillance, Alerting and Response: Develops algorithms that generate and disseminate warning to personnel in time to prevent exposure to or limit the impact of CBRN threats. This thrust area conducts data collection trials to support algorithm development; leverages Artificial Intelligence to identify key indicators, combinations of indicators, and sensing modalities to reduce false alarms and predict the likelihood of exposure; explores remote and contactless monitoring and analysis for application in Warfighter chemical and biological threat exposure alerting. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.</p> <p>Diagnostic Building Blocks: Develops foundational capabilities for the entire diagnostics portfolio; invests in innovative, cutting-edge technologies to improve the development pipeline for diagnostics; and exploits areas in artificial intelligence synthetic biology and machine learning to develop novel and rapid diagnostic tests for utilization. Efforts accelerate assay development timelines and optimize test parameters by leveraging novel concepts and tools that readily allow a pivot to assay development for emerging threats.</p> <p>Emerging Threats: Invests in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure, to greatly advance efficacy rates and turnaround time for Warfighter wellness. Efforts focus on better preparing for surprise by developing diagnostic systems that leverage novel approaches to characterize pathogens or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample.</p> <p>Battlefield Readiness: Provides innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provides diagnosis at lower roles of care. Develops field forward medical diagnostics to provide multiplexed detection of biological and toxin threats and leverages immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.</p> <p>CBRN Decision Aids: Provides tools that assess risk from CBRN hazards and identifies courses of action to limit impact. This thrust area permits connectivity, enabling the dynamic discovery, querying, and control of sensors through standard protocols; and allows for dynamic discovery and integration between networked devices at the tactical edge to enable sharing of information and capabilities across connected components.</p> <p>CBRN Situational Awareness: Provides operationally relevant context to CB-specific phenomena data to ensure the Joint Force is able to characterize new CB hazards and mitigate their effects on mission success. This thrust area provides the analytic framework to determine optimal defense postures by extrapolating scientific data generated during the course of technology development and hazard assessment data into an assessment to inform operational utility. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.</p> <p>Enhanced and Emerging Biothreat Sensing: Establishes a capability to rapidly develop advanced, agile, pathogen-agnostic laboratory and field forward detection capabilities to detect emerging and enhanced biological threats across all force echelons (presumptive, field confirmatory, theater validation, and definitive identification).</p>		

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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Further, multiple biological measurements will be used to modernize laboratory capabilities and leverage synthetic biology methods and tools to deliver enhanced biothreat sensing/detection capabilities to the Joint Force.

Technical Surprise: Encompasses horizon scanning to identify potential areas of concern and conducts technical assessments of emerging technological advancements. Efforts assess technological advancements for potential implications to the threat space, including agent use and release and develops capabilities to evaluate and assess technical enhancements that may alter the nature or magnitude of a threat agent.

Clinical Evaluation: Provides independent verification and validation of diagnostic tests in real world patients to decrease development costs, collecting initial clinical data sets to support pre-submission discussions with the Food and Drug Administration (FDA). De-risks diagnostic platform development through third party, real world, and austere environment testing and evaluation prior to transition and establishes clinical and performance parameters therefore de-risking diagnostic platforms through real world populations.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
<p>Title: 1) Material Contamination Mitigation</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional CWAs, including pharmaceutical based agents. Coordinate with the Intelligence Community (IC) to understand the chemical threat space, adapting capabilities to meet the need.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue efforts that expand the capability of wearable devices from an alert to an FDA-approved diagnostic platform that can detect a chemical threat and allow a physician to diagnose and determine a treatment strategy for exposure to traditional/nontraditional chemical agents. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$3.710 Million) remains in TM3.</p>	-	-	1.914
<p>Title: 2) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Transition stand-off detector prototypes that identify and alert to chemical hazards to Proximate Chemical Agent Detector (PCAD) Program of Record. - Continue development toward detection prototypes to address pharmaceutical based agent (PBA) and other emerging threats. 	-	-	17.664

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue the development of sensor technologies against non-traditional threats of concern to develop class-based detection and reduce reliance on known threat libraries.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB3 and NT3.</p>				
<p>Title: 3) Unattended Perimeter Monitoring</p> <p>Description: Establish a layered defense capability by developing and implementing automated and integrated technologies enabling unattended monitoring for chemical and biological threats. These technologies will provide early warning of vapor, aerosol, solid, and liquid hazards and unencumber the Warfighter by reducing logistics and operator burden. Providing a reliable detect-to-warn capability at fixed or expeditionary sites will enhance the overall protective posture of ground and maneuver forces as robust technologies can be miniaturized for portability and operational sustainment.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Transition automated biological collection, detection and identification system. Fully autonomous system will reduce errors by eliminating the need for laboratory personal to perform analysis. - Initiate efforts to modernize capabilities to reduce false alarms and increase sensitivity and specificity. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.094 Million) remains in CB3.</p>		-	-	1.177
<p>Title: 4) Diagnostic Building Blocks</p> <p>Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats in days instead of weeks.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate field validation studies for diagnostics prototypes using synthetic binders and evaluate performance against current gold standard diagnostic methods. - Continue efforts to collect the baseline data required for future development of a whole breath diagnostic platform use of breath as a non-invasive sampling mechanism offers Warfighters little-to-no interruption to mission activities and provides the opportunity for earlier diagnosis/indication of infection or chemical exposure. - Continue executing data transitions for the development of diagnostic assays to support vaccine and countermeasure development efforts. 		-	-	4.786

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Complete a joint effort with CBDP Components to establish an assay development and manufacturing process that would allow DoD laboratories to be authorized assay developers, enabling the DoD to develop assays against emerging threats and diseases to quickly be functionalized for the fielded Next Generation Diagnostics System (NGDS) 2 Man Portable Diagnostic System (MPDS) platform.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.950 Million) remains in TM3.</p>				
<p>Title: 5) Emerging Threats</p> <p>Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.</p> <p>FY 2023 Plans:</p> <p>- Complete efforts to address challenges in small molecule toxin diagnosis at the point of contamination (POC) and initiate validation of these prototypes for potential use as a threat agnostic capability to enable field-forward responses to emerging threats.</p> <p>- Complete the development of a universal blood sample preparation platform to be compatible with several diagnostic systems, improving the speed of sample preparation tools at low pathogen concentrations (i.e. pre-symptomatic levels) is one of the biggest challenges holding back diagnostics in point-of-care, outbreak, and remote testing scenarios.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$2.473 Million) remains in TM3. Increase due to change in program/project technical parameters.</p>		-	-	3.828
<p>Title: 6) Battlefield Readiness</p> <p>Description: Develop platforms to prepare the Warfighter with rapid and easy to use diagnostics tests to make sure they are healthy and ready for movement. Platforms developed with affinity-based identification of either pathogen or host response to the pathogen may leverage immunodiagnostics to identify specific targets using antibodies, or explore other innovative approaches. This will enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. Investments in this area will provide capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care.</p> <p>FY 2023 Plans:</p>		-	-	6.700

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
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<ul style="list-style-type: none"> - Complete the development and evaluation of a customizable, lightweight, comfortable, in ear wearable device (EWD) and algorithms to detect disease onset by monitoring a Warfighter's health state. - Complete the development of vertical flow assay technologies that are rapid, capable of multiplexing, portable, and may result in a faster sample to answer and more sensitive detection level than traditional lateral flow diagnostics. - Complete the program to identify biological indicators that predict disease severity, which will lead to the development of a diagnostic that alerts medical personnel that a patient's condition may worsen or require immediate intensive care. - Continue a wearable effort for developing and testing a microneedle-based patch intended to screen for the presence of a viral or bacterial infection, this focus on minimally invasive testing techniques along with easy to use wearables will further support DoD mission readiness. - Continue the development of a POC diagnostic platform that can provide the Warfighter pre-symptomatic diagnosis of infection, irrespective of whether the underlying pathogens are viral, bacterial, or parasitic. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$7.774 Million) remains in TM3. Decrease due to change in technical parameter.</p>			
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<p>Title: 7) CBRN Decision Aids</p> <p>Description: In order to unencumber the warfighter at the tactical edge, continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards. Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue developing new decision support plug-ins for integration with Tactical Assault Kit (TAK), including the Android, web, Windows OS, and virtual and augmented reality versions, to further enhance the TAK infrastructure and cross-community tools and develop a rapid and iterative software capability. - Complete development of GPU-based faster-than-real-time, high resolution hazard prediction modeling capabilities and continue user testing. - Finalize the development of approaches to translate raw sensor data and publish to a common standard. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	-	-	3.000
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$1.400 Million) remains in CB3. Increase due to change in program/project technical parameters.				
<p>Title: 8) Emerging and Enhanced Biothreat Sensing</p> <p>Description: Establish robust capability to assess emerging and enhanced biological threats to rapidly develop biosensors for detecting emerging or enhanced biological threats. Quickly develop adaptable, analyte-agnostic laboratory and field-forward detection capabilities to provide a spectrum of improved detection assets for novel threats. This thrust area leverages multi-omics data science or the combining multiple measurements to inform rational and rapid design and development of biodetection solutions. Synthetic biological concepts will be thoroughly evaluated and exploited for the development of biosensing solutions and refinement of laboratory methods.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection and identification capabilities that discern if pathogens are genetically manipulated and/or identify pathogens of unknown origin. - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Transition far-forward pathogen agnostic sensing toolkit to provide on-site threat identification while reducing the burden on the Warfighter by using technologies that rely on little to no supply chain disposables. - Continue development of on-demand biological threat detection assays that provide the Warfighter with the ability to rapidly respond to emerging biological threats and provide only the assay needed for threat identification and therefore reducing cost and reagents needed by most current assay kits. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$2.848 Million) remains in CB3. Increase due to change in program/project technical parameters.</p>		-	-	3.169
<p>Title: 9) Battlefield Readiness - Biodefense Improvement Program</p> <p>Description: Provide non-invasive disease screening capabilities to rapidly respond to emerging biological threats and greatly enhance the Warfighters ability to seek medical treatment at the earliest indication of exposure. These funds support the Biological Defense Improvement Program (BDIP).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Expand the development of existing wearable monitors that are capable of detecting chemical threats and adapt the devices to include detection of biological pathogen exposure. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	2.000

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Increase due to accelerated development effort.				
<p>Title: 10) CBRN Battlespace Surveillance, Alerting & Response</p> <p>Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. Efforts will expand on developing predictive CB exposure algorithms based on non-invasively collected human biomarkers. Current predictive algorithms in development are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue the improvement of algorithms that leverage non-invasive based physiological data to provide early warning of chemical and biological threats and/or exposure. - Continue the advancement of standoff physiological monitoring capabilities. - Leverage a data and AI platform that supports access to harmonized physiological status monitoring data and support development and validation of models to continue to develop predictive algorithms aimed at the rapid response to Emerging Threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$4.848 Million) remains in CB3. Increase due to change in program/project technical parameters.</p>		-	-	5.171
<p>Title: 11) CBRN Battlespace Surveillance, Alerting & Response - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on CBRN Decision Aids CBRN Battlespace Surveillance Alerting, & Response - Biothreat Characterization, Data Analysis & Modeling. A passive, wearable, contactless screening capability would greatly enhance the Warfighters ability to seek medical treatment at the earliest indication of exposure. This area includes data collection and analysis of exposure data; competitive prototyping to further develop algorithms that are able to non-invasively identify afflicted personnel and inform courses of action, prior to the onset of symptoms; expansion of efforts to develop analytic resources for early warning/ decision support; examining physiological effects on human tissue in multi-organ-chips after exposure to CB threat agents; and S&T for an advanced, integrated cloud based data environment to store a dynamic knowledge base of biothreat characteristics.</p> <p>FY 2023 Plans:</p>		-	-	3.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>- Examine feasibility of isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure.</p> <p>- Leverage competitive prototyping to explore and evaluate alternative concepts for providing remote sensing and/or minimally- and non-invasive techniques to enhance our ability to quickly identify afflicted personnel and inform courses of action, ideally prior to the onset of symptoms.</p> <p>- Development of an advanced, integrated cloud based data environment to store a dynamic knowledge base of biothreat characteristics; capability would support automated data ingestion, collection, curation, search, and advanced analytics of data.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>			
<p>Title: 12) CBRN Situational Awareness</p> <p>Description: To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled. Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models. Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield. JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems. JSTO will further enhance hazard modeling by creating a seamless indoor- to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy. JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue configuration management of science and technology prototype for transition of upgraded capabilities. - Continue improvement of performance enhancements for T&D models, particularly for urban environments. - Continue the development of comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. 	-	-	3.888

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue to enhance CB situational awareness capabilities for integration into Head up Display (HUD) technologies for tactical use.</p> <p>- Build out pipelines for ingestion and storage of disparate chemical and biological threat datasets and advanced analytic development to support the CBDP medical enterprise.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$5.016 Million) remains in CB3. Decrease due to change in program/project technical parameters.</p>				
<p>Title: 13) CBRN Situational Awareness - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on CBRN Decision Aids CBRN Battlespace Surveillance Alerting, & Response - Biothreat Characterization, Data Analysis & Modeling. Explore solutions for comprehensive biothreat characterization in support of CBDP biodefense modernization goals, including the development of data analytics using ML/AI and efforts to provide a suite of analytic tools for biological threat agent modeling, forecasting, and prediction to determine optimal defense postures. Utilize scientific data generated during the course of technology development and hazard assessment data) to help inform operational utility. Epidemiological models will be developed that quantify risk and visualize mission operational impacts accounting for medically relevant inputs from exposure to and spread of CB threat agents of relevance to DoD.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Expand development of analytic tools for biological threat agent surveillance, modeling, forecasting, and prediction. - Accelerate and expand efforts to develop data analytics using ML/AI to predict individual warfighter susceptibility to acute CB agent exposure based on advanced omics, epigenetics, host immune responses, and wearables data sources. - Explore feasibility of mathematical models for innate immune recognition based on clinical data and prediction of signature patterns associated with bacterial vs. viral pathogens <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	3.000
<p>Title: 14) Clinical Evaluation</p> <p>Description: Optimize the diagnostic development pathway by incorporating independent testing and evaluation for more informed prototype transition prior to advanced development. Investments in this area allow e evaluation of diagnostic platforms through real world, austere environment testing. This area maintains access to research sites that offer native populations exposed to diseases of interest that would affect the Warfighter in battlefield settings, and provides the ability to acquire novel technologies and provide analytical testing, evaluation, and reach back support for technologies already fielded.</p> <p>FY 2023 Plans:</p>		-	-	1.914

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) UN3 / Understand (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating.</p> <p>- Initiate independent third-party testing - to establish clinical and performance parameters to evaluate diagnostic platforms through real world, austere environment testing and evaluation prior to transition.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$3.210 Million) remains in TM3. Decrease due to change in technical parameter.</p>				
<p>Title: 15) Diagnostic Building Blocks - Biodefense Improvement Program</p> <p>Description: Provide agile assay development capabilities aided by Artificial Intelligence (AI) to advance the speed and accuracy of diagnostic assay design, addressing a key functional capability needed for emerging biological threat response. These funds support the Biological Defense Improvement Program (BDIP).</p> <p>FY 2023 Plans: - Expand the development of agile biological assays to reduce the design assay and increase assay quality to better respond to emerging biological threats.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Increase due to accelerated development effort.</p>		-	-	1.500
<p>Title: 16) Distributed Biological Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/ collection systems that are rugged, rapid and accurate. Early indications from capabilities under CB Reconnaissance will allow for enhanced warning of threats.</p> <p>FY 2023 Plans: - Continue to develop innovative sensor solutions to increase situational threat awareness and provide operational advantage. - Continue to develop low-cost, low Size, Weight and Power (SWaP), and low-burden, with little to no dependence on supply chain, detection technologies to support of tactical and dismounted site assessment missions. - Continue to enhance sensing capabilities for unmanned vehicles and its integration into mobile platforms.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	1.598

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) UN3 / Understand (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$2.079 Million) remains in CB3. Decrease due to change in program/project technical parameters.				
<p>Title: 17) Distributed Chemical Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete aerosol microsensor development. - Development toward a deployable microsensor development pipeline and enhance sensor integration efforts. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$2.407 Million) remains in NT3.</p>		-	-	3.157
<p>Title: 18) Emerging and Enhanced Biothreat Sensing - Biodefense Improvement Program</p> <p>Description: Provide end users with a rapid assay capability (< 6 weeks from discovery of emerging/enhanced threat to delivery of the initial assay) that will be disruptive to current detection and diagnostic timelines. Eliminate the need to rely on single-source reagents to rapidly respond to emerging biological threat. These funds support the Biological Defense Improvement Program (BDIP).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Accelerate assay development to provide rapid, agile, and scalable biodetection technology to quickly address emerging biological threats and allow the Warfighter to use a highly-specific assay that is built to minimize logistics burden and is user-friendly. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Increase due to accelerated development effort.</p>		-	-	2.200
<p>Title: 19) Emerging Threats - Biodefense Improvement Program</p> <p>Description: Expand on agnostic disease screening and sensing capabilities for emerging biological threats. These funds support the Biological Defense Improvement Program (BDIP).</p> <p>FY 2023 Plans:</p>		-	-	1.000

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) UN3 / Understand (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Expand investments in agnostic sensing/screening capabilities for multiple sample types and environments that are end user-friendly and can be deployed in the field.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Increase due to accelerated development effort.</p>				
<p>Title: 20) Technical Surprise - Biodefense Improvement Program</p> <p>Description: Technical Surprise assesses technological advancements for potential implications to the threat space, including agent use and release. Technical Surprise includes horizon scanning to identify potential areas of concern as well as conducts technical assessments of emerging technological advancements (e.g. biotechnology, artificial intelligence, machine learning, quantum computing). This program develops capabilities to evaluate and assess technical enhancements that may alter the nature or magnitude of a threat agent. The technical surprise program will be evaluating technologies and convergence of technologies that improve the ease of threat use and make threats more likely to survive being released. The program will identify the limitations and barriers associated with synthetic biology and assess the implications. And finally, these efforts will identify and assess former technology hurdles that have been lowered or overcome and assess implications of increasing potential threat. These funds support the Biological Defense Improvement Program (BDIP).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Identify and assess technological advancements that will impact the biological threat space, including potential threats that have implications to biological defense capabilities. - Use horizon scanning capability to provide situational awareness in assessing technological growth and convergence that can affect the threat space, while keeping abreast of changes in the nature of future threats. - Assessment of synthetic biological tools and other biotechnology developments that can enhance or alter the threat space. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Increase due to accelerated development effort.</p>		-	-	3.000
<p>Title: 21) Unconventional Biological Detection Modalities</p> <p>Description: Develop disruptive technologies to identify unknown or emerging biological threats and develop biological sensors that can operate in complex threat environments with high fidelity. This effort supports the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete development and refinement of integrated photonics. - Complete development and refinement of miniaturized Raman spectrometers. - Complete development and refinement of machine learning algorithms for integrating disparate sensor feeds. 		-	-	0.871

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) UN3 / Understand (ATD)
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
- Initiate library-less detection efforts to move towards threat agnostic detection and provide rapid-fielded capabilities to address emerging biological threats. - Continue development of state of the art size and speed of detection technologies that include advances in computational tools, Artificial Intelligence (AI)/Machine Learning (ML) to address the most difficult changes in biological detection. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure.			
Title: 22) Unconventional Chemical Detection Modalities Description: Develop disruptive technologies to identify unknown or emerging chemical threats and develop chemical sensors that can operate in complex threat environments with high fidelity. This thrust area supports other thrust areas and as needed the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance). FY 2023 Plans: - Complete development and refinement of integrated photonics. - Complete development and refinement of miniaturized Raman spectrometers. - Complete development and refinement of machine learning algorithms for integrating disparate sensor feeds. - Initiate library-less detection efforts to move towards threat agnostic detection and provide rapid-fielded capabilities to address emerging chemical threats. - Continue development of state of the art size and speed of detection technologies that include advances in computational tools, Artificial Intelligence (AI)/Machine Learning (ML) to address the most difficult changes in chemical detection. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB3 and NT3.	-	-	1.485
Accomplishments/Planned Programs Subtotals	-	-	76.022

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• UN4: Understand (ACD&P)	0.000	0.000	57.908	-	57.908	55.291	59.174	57.358	33.474	Continuing	Continuing

Remarks

D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) ET3 / Emerging Threats (ATD)
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
ET3: <i>Emerging Threats (ATD)</i>	-	0.000	6.000	0.000	-	0.000	10.000	10.000	10.000	10.000	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project ET3 aims to identify and develop scientific solutions, or to modernize capabilities, that allow for a more rapid response to emerging threats. This project supports the development of defense capabilities, collaborating across the DoD and specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against emerging threats. Additionally, this project supports advanced development of defensive science and technology capabilities aimed at proactive characterization of threats and potentially disruptive technologies.

Individual efforts in this Project include:

- Developing new science and technology capabilities that allow for the rapid characterization of emerging threats to support operational decision making and requirements setting. Support an integrated approach to developing new or enhanced countermeasures against emerging threats through innovative science and technology solutions for detection, protection, decontamination, and medical countermeasures (MCMs).
- Efforts supply test methodologies and supporting science to verify capabilities, develop protection and hazard mitigation options, expand hazard assessment tools, and develop MCMs against emerging threats.

Chemical and Biological Emerging Threat Innovation Fund challenge DoD Labs and innovation cells to deliver transformational technologies against emerging threats that enables the force to compete, deter, and win in strategic environments described in the National Defense Strategy.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Emerging Threat Innovation	-	6.000	-
Description: The Chemical and Biological Defense Emerging Threat Innovation Fund challenges DoD Labs and innovation cells to deliver transformational technologies against emerging threats that enables the force to compete, deter, and win in strategic environments described in the National Defense Strategy.			
FY 2022 Plans: Initiate enhanced capability to more rapidly characterize, and the development of medical countermeasures against, emerging chemical and biological threats through investment in high throughput technologies.			
FY 2022 to FY 2023 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.			
Accomplishments/Planned Programs Subtotals	-	6.000	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) ET3 / Emerging Threats (ATD)

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>			<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u>	
			<u>Base</u>	<u>OCO</u>	<u>Total</u>					<u>Complete</u>	<u>Total Cost</u>
• CA4: Contamination Avoidance (ACD&P)	9.367	32.923	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	42.290
• DE4: Decontamination (ACD&P)	4.919	18.385	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	23.304
• IP4: Individual Protection (ACD&P)	3.448	3.968	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	7.416
• MT4: Mitigate (ACD&P)	0.000	0.000	20.986	-	20.986	13.556	12.702	20.846	18.167	Continuing	Continuing
• PT4: Protect (ACD&P)	0.000	0.000	203.689	-	203.689	183.220	139.375	113.754	105.176	Continuing	Continuing
• TE4: Test & Evaluation (ACD&P)	4.107	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	4.107
• UN4: Understand (ACD&P)	0.000	0.000	57.908	-	57.908	55.291	59.174	57.358	33.474	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) CB3 / Chemical Biological Defense (ATD)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
CB3: <i>Chemical Biological Defense (ATD)</i>	-	26.844	26.950	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	53.794
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project CB3 develops technology advancements for joint service application in the areas of digital battlespace management technologies, protection/ hazard mitigation and detection. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. In FY23, the CBDP RDT&E Projects have been restructured to align to the CBDP portfolio. CB3 thrust areas in FY22 progress to the Mitigate (MT3), Protect (PT3), and Understand (UN3) portfolios. This restructuring is intended to provide standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this project include:

- Digital battlespace management focuses on situational awareness and threat agent applications, analytic applications platform for operational situational awareness, non-traditional detection sciences, tactical decision aids, and advanced computational methods.
- Protection/hazard mitigation works to provide technologies that protect from and reduce the impact of both chemical and biological threats and hazards to the Warfighter, weapons platforms, and structures.
- Detection strives to develop technologies for point and standoff detection and identification of both chemical and biological agents.
- Non-Traditional Agent (NTA) Defense includes chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Air Purification Enhancements	0.270	0.287	-
Description: This effort supports the Expeditionary Collective Protection (CP). Existing CP systems have high life cycle costs driven by maintenance and limited service life. Science & Technology efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.			
FY 2022 Plans:			
- Continue materials testing for effectiveness against novel threats for Next Generation Filtration systems.			
- Incorporate novel materials into Collective Protection (ColPro) systems that increase the performance against agents delivered in all states of matter (vapor, aerosol, and liquid) in operationally relevant environments.			
- Engineer novel filter bed materials for chemical agent destruction, integrate them into next generation filters, and develop methods to assess filter performance in an operationally-relevant environment.			
FY 2022 to FY 2023 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.287 Million) transferred to PT3.				
<p>Title: 2) All-Hazards & Respiratory Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit Self-Contained Breathing Apparatus.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Transition lightweight protective garment for all hazards environments to Uniform Integrated Protection Ensemble Family of Systems Program of Record - Complete development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Develop next generation respiratory protection technology in the form of a low-burden, non-contact powered respirator with novel filter designs that integrates with Warfighter technologies and reduces encumbrance. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.345 Million) transferred to PT3.</p>		1.962	0.814	-
<p>Title: 3) Multifunctional Materials for Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Materiel Contamination Mitigation, and Personnel Contamination Mitigation. Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials (derived from BA2 efforts) into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Test and transition self-decontaminating, reusable protective garments (derived from BA2 efforts) of composite textiles with a reactive barrier, improved protection, and reduced thermal burden/life-cycle costs for insertion into the Uniform Integrated Protection Ensemble Family of Systems Program of Record. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		1.439	1.040	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding transferred to CB3 and MT3.				
<p>Title: 4) CBRN Battlespace Surveillance, Alerting & Response</p> <p>Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. JSTO will expand on developing predictive CB exposure algorithms based on non-invasively collected human biomarkers. Current predictive algorithms in development by JSTO are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue the improvement of algorithms that leverage non-invasive physiological monitoring devices to provide earlier warning of chemical and biological threats and/or exposure. - Continue the advancement of standoff physiological monitoring capabilities. - Continue to develop predictive algorithms and analytic tools utilizing Artificial Intelligence (AI) and ML techniques to allow for rapid response to Emerging Threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$5.171 Million) transferred to UN3.</p>		1.840	4.848	-
<p>Title: 5) CBRN Decision Aids</p> <p>Description: In order to unencumber the warfighter at the tactical edge, continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards.</p> <p>Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the</p>		1.035	1.400	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue the improvement of decision support plug-ins for integration with TAK, including the Android, web, Windows OS, and virtual and augmented reality versions to further leverage the TAK infrastructure and cross-community tools. - Further develop the use of GPUs for faster than real-time high resolution hazard prediction modeling capabilities and initiate user testing. - Finalize the development of approaches to translate raw sensor data and publish to a common standard. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.000 Million) transferred to UN3.</p>			
<p>Title: 6) CBRN Situational Awareness</p> <p>Description: To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled.</p> <p>Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models. Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield.</p> <p>JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems. JSTO will further enhance hazard modeling by creating a seamless indoor- to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy.</p> <p>JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from</p>	4.428	5.016	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue configuration management of science and technology prototype for transition of upgraded capabilities. - Continue improvement of performance enhancements for T&D models, particularly for urban environments. - Continue the development of comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. - Continue to enhance CB situational awareness capabilities for integration into Head up Display (HUD) technologies for tactical use. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.888 Million) transferred to UN3.</p>			
<p>Title: 7) Distributed CB Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/ collection systems that are rugged, rapid and accurate. Early indications from capabilities under CB Reconnaissance will allow for enhanced warning of threats.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Incorporate sensors into maneuver autonomy to enhance biological threat reduction. - Develop innovative sensor solutions to increase situational awareness and provide operational advantage. - Sensor development will include integration of technologies such as photonics and Waveguide-Enhanced Raman Spectroscopy (WERS) into detectors as sensor arrays. - Develop low-cost, low-burden detection technologies to support tactical and dismounted site assessment missions. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.598 Million) transferred to UN3.</p>	3.055	2.079	-
<p>Title: 8) Enhanced/Emerging Biothreat Sensing</p> <p>Description: Establish robust capability to assess emerging and enhanced biological threats to rapidly develop biosensors for detecting emerging or enhanced biological threats. Quickly develop adaptable, analyte-agnostic laboratory and field-forward detection capabilities to provide a spectrum of improved detection assets for novel threats. This thrust area leverages multi-omics data science or the combining multiple measurements to inform rational and rapid design and development of biodetection</p>	1.680	2.848	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>solutions. Synthetic biological concepts will be thoroughly evaluated and exploited for the development of biosensing solutions and refinement of laboratory methods.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection capabilities focused on addressing emerging biological threats. - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Continue development of far-forward pathogen agnostic sensing toolkit. - Continue development of in-silico design to expedite assay development. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.169 Million) transferred to UN3.</p>				
<p>Title: 9) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Develop a suite of expeditionary chemical sensors to provide the warfighter with modernized detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of chemical vapor sensor utilizing dielectric excitation with focus prototype delivery and validation. - Continue development of sensors based on semiconductor thin films coated with plasmonic metal and metal oxide nanoparticles; focus on validation and testing systems. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.318 Million) transferred to UN3.</p>		2.929	3.333	-
<p>Title: 10) Unattended Perimeter Monitoring</p> <p>Description: Establish a layered defense capability by developing and implementing automated and integrated technologies enabling unattended monitoring for chemical and biological threats. These technologies will provide early warning of vapor, aerosol, solid, and liquid hazards and unencumber the Warfighter by reducing logistics and operator burden. Providing a reliable detect-to-warn capability at fixed or expeditionary sites will enhance the overall protective posture of ground and maneuver forces as robust technologies can be miniaturized for portability and operational sustainment.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Evaluate technology for next generation UAV-borne and wearable approaches - Integrate automated technologies to improve stand-off detection of vapor, aerosol, solid and liquid hazards for chemical detection. 		0.884	1.094	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
- Integrate refined trigger, collector, and detector/identifier technologies for bioaerosol detection.				
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.177 Million) transferred to UN3.				
Title: 11) Unconventional Detection Modalities Description: Utilize a targeted set of programs pushing the boundaries of sensor development by pulling technologies developed from academia and basic research to be integrated into early detection prototypes. These technologies focus on keeping the warfighter ahead of the chemical and biological threats with portable, low SWaP detectors that will protect the general forces and enhance operations on the battlefield by providing warning and field analytics. FY 2022 Plans: - Continue model development for machine learning algorithms. - Continue development of detection of emerging biothreats using cell-free platforms onto an integrated prototype. - Conduct detection sensing validation for detection by utilizing nanoparticles and voltammetry electrochemistry. - Conduct model testing and validation of machine learning algorithms for chemical detection sensors. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.871 Million) transferred to UN3.		1.085	0.781	-
Title: 12) Lightweight Protective Garments Description: This effort supports the Percutaneous Protection. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments. FY 2022 Plans: - Transition improved protective garment test methodologies (derived from BA2 efforts) that provide greater validation of CB protection, are repeatable and support testing under relevant conditions to the Uniform Integrated Protection Ensemble Family of Systems Program of Record. - Continue assessment for antimicrobial fabrics (derived from BA2 efforts) to be used as inner layer/liner in protective uniforms to prevent excessive growth of microbes associated with hygiene/extended wear and reduce the need for laundering. FY 2022 to FY 2023 Increase/Decrease Statement: Minor change due to routine program adjustments. This effort was funded under Percutaneous Protection.		-	0.144	-
Title: 13) Dynamic Multifunction Materials for Second Skin		-	1.313	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Description: This effort supports the Percutaneous Protection. Efforts will utilize responsive technologies to provide CB protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Increase molecular selectivity of responsive interpenetrating polymers (derived from BA2 efforts) towards nerve and blister agents. - Demonstrate and scale carbon nanotube membrane responsive textiles (derived from BA2 efforts) efforts into garments that increase protection levels in response to chemical weapons agents while preserving moisture vapor transport rate. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.149 Million) transferred to PT3.</p>			
<p>Title: 14) Enhanced Survivability Coatings</p> <p>Description: This effort supports the Materiel Contamination Mitigation. Military equipment coatings are challenging and logistically intensive to decontaminate. Efforts within this thrust seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Increase chemical agent resistance of current military coatings through development and testing of novel temporary coatings to reduce the spread of contamination and enable more facile decontamination of military assets. Improve success of decontamination through the evaluation and incorporation of appliques. - Characterize chemical transport in current military coatings, thin film overcoats, and strippable, reactive, and lock-down coats in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY23 funding (\$0.416 Million) transferred to MT/PT3.</p>	0.198	0.345	-
<p>Title: 15) Equipment Decontamination</p> <p>Description: This effort supports the Materiel Contamination Mitigation. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking;</p>	1.983	0.649	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022	
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022
<p>reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Begin integrating contamination mitigation technologies by advancing the proof of concept for hot-air CWA decontamination by validating the operational performance envelope. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements. - Transition Sprayable Decontaminant Slurry technology for immediate chemical warfare agent decontamination of equipment to the Service Equipment Decontamination System (SEDS) Program of Record. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.951 Million) transferred to MT3.</p>			
<p>Title: 16) Personnel Decontamination</p> <p>Description: This effort supports the Personnel Contamination Mitigation. Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a CWA exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue investigations to optimize form factors for dry skin decontamination. - Develop and assess physical removal technologies for potential replacement of RSDL. - Continue to integrate new dry decontamination into a mitt form factor and determine S&T challenges within process and procedure improvements. This includes development of methodologies and procedures for military working dog (MWG) decontamination. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.854 Million) transferred to MT3.</p>		1.056	0.959
Accomplishments/Planned Programs Subtotals		23.844	26.950
		FY 2021	FY 2022
Congressional Add: High Air Flow ChemBio Filtration System Enhancement		3.000	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) CB3 / Chemical Biological Defense (ATD)

	FY 2021	FY 2022
FY 2021 Accomplishments: Develop High Air Flow ChemBio Filtration System Enhancement for expeditionary and mobile collective protection systems through combination of filter elements, incorporation of new filter bed materials, and reduction of element size.		
Congressional Adds Subtotals	3.000	-

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• CA4: Contamination Avoidance (ACD&P)	9.367	32.923	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	42.290
• DE4: Decontamination (ACD&P)	4.919	18.385	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	23.304
• MT4: Mitigate (ACD&P)	0.000	0.000	20.986	-	20.986	13.556	12.702	20.846	18.167	Continuing	Continuing
• TT4: Technology Transition (ACD&P)	0.577	0.866	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.443
• UN4: Understand (ACD&P)	0.000	0.000	57.908	-	57.908	55.291	59.174	57.358	33.474	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
NT3: <i>Non-Traditional Agents Defense (ATD)</i>	-	13.001	18.396	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	31.397
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project NT3 develops future capabilities against emerging and novel threats and verifies current capabilities against Non-Traditional Agents (NTAs). This project focuses on demonstrating fast and agile scientific responses to enhance or develop capabilities that address emerging threats. This project is a comprehensive and focused effort for developing NTA defense capabilities, coordinated with specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against NTAs. This project supports advanced technology development of NTA defense science and technology initiatives and transitioning to advance development. In FY2023, the CB DP RDT&E Projects have been restructured to align to the CB DP portfolio. NT3 thrust areas in FY2022 progress to the Understand (UN3) portfolio. This restructuring is intended to provide standardization and alignment across CB DP research, development and acquisition efforts.

Individual efforts in this Project include:

- Support an integrated approach to develop new or enhanced countermeasures against novel and emerging threats through innovative science and technology (S&T) solutions for detection, protection, decontamination and medical countermeasures (MCMs).
- Efforts supply test methodologies and supporting science to verify capabilities, develop protection and hazard mitigation options, expand hazard assessment tools, and develop MCMs against NTAs.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Distributed CB Reconnaissance	1.500	2.407	-
Description: : Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate.			
FY 2022 Plans:			
- Validate testing of miniature aerosol sensors that selectively detect presence of airborne particles.			
- Model the response of passive biomimetic sensor capability to detect chemical threat simulants and interferents for identification.			
FY 2022 to FY 2023 Increase/Decrease Statement:			
Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.157 Million) transferred to UN3.			
Title: 2) Expeditionary Analytical Toolkit (ExAnT)	10.103	14.166	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p> <p>FY 2022 Plans: - Continue the development of sensor technologies against non-traditional threats of concern to develop class-based detection and reduce reliance on known threat libraries.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$14.346 Million) transferred to UN3.</p> <p>Title: 3) Unconventional Detection Modalities</p> <p>Description: Develop disruptive technologies to identify unknown or emerging chemical threats and develop chemical sensors that can operate in complex threat environments with high fidelity. This thrust area supports other thrust areas and as needed the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2022 Plans: - Continue development and refinement of integrated photonics. - Continue development and refinement of miniaturized Raman spectrometers. - Continue development and refinement of machine learning algorithms for integrating disparate sensor feeds.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.485 Million) transferred to UN3.</p>			
Accomplishments/Planned Programs Subtotals	1.398	1.823	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• CA4: Contamination Avoidance (ACD&P)	9.367	32.923	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	42.290
• DE4: Decontamination (ACD&P)	4.919	18.385	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	23.304
• IP4: Individual Protection (ACD&P)	3.448	3.968	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	7.416
• MT4: Mitigate (ACD&P)	0.000	0.000	20.986	-	20.986	13.556	12.702	20.846	18.167	Continuing	Continuing
• PT4: Protect (ACD&P)	0.000	0.000	203.689	-	203.689	183.220	139.375	113.754	105.176	Continuing	Continuing
• UN4: Understand (ACD&P)	0.000	0.000	57.908	-	57.908	55.291	59.174	57.358	33.474	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	Project (Number/Name) NT3 / <i>Non-Traditional Agents Defense (ATD)</i>

C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
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Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)			Project (Number/Name) TM3 / Techbase Medical Defense (ATD)				
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
TM3: Techbase Medical Defense (ATD)	-	134.162	137.691	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	271.853
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project TM3 supports preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. In FY2023, the CBDP RDT&E Projects have been restructured to align to the CBDP portfolio. TM3 thrust areas in FY2022 progress to the Enabling Investments (EN3), Mitigate (MT3), Protect (PT3), and Understand (UN3) portfolios. This restructuring is intended to provide standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this project include:

- Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated.
- Rapid development of medical countermeasure solutions is a crucial modernization strategy to avoid technological surprise against an expanding and sophisticated biological WMD threat. Techbase Medical Defense (ACD&P), therefore, supports the Discovery of Medical Countermeasures Against New and Emerging (DOMANE) threat thrust, which is designed to develop technologies that support understanding, mitigating, and protecting against new and emerging biological threats to include viral, bacterial, and biotoxins.
- Supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes and therapeutic drugs against new and emerging biological threats. Demonstration of safety and toxicity data through adaptive trials for repurposed FDA-approved drugs, novel broad-spectrum drugs and drug combinations supporting submitting Investigational New Drug (IND) processes or Emergency Use Authorizations (EUA). Additionally, this effort supports development of technologies that protect, mitigate and understand new and emerging threats by forecasting pathogenesis and toxicity, structural determinations utilizing high throughput systems to identify both host and pathogen targets using advanced AI and a curated repository of high-resolution 3D macromolecular structures to generate drug candidates.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Internal COVID - VSV SARS CoV-2 vaccine	-	5.100	-
Description: Provide the Warfighter with protection against COVID-19 through the development of a SARS CoV-2 VSV vaccine.			
FY 2022 Plans: Complete pre-clinical development of the Vesicular Stomatitis Virus - delta G (VSV-deltaG) SARS CoV-2 vaccine.			
FY 2022 to FY 2023 Increase/Decrease Statement:			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Decrease due to accelerated development effort. Supports COVID-19/pandemic response efforts.			
<p>Title: 2) Battlefield Readiness</p> <p>Description: Develop platforms to prepare the Warfighter with rapid and easy to use diagnostics tests to make sure they are healthy and ready for movement. Platforms developed with affinity-based identification of either pathogen or host response to the pathogen may leverage immunodiagnosics to identify specific targets using antibodies, or explore other innovative approaches. This will enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. Investments in this area will provide capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete the development a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset. - Complete the development and evaluation of a customizable, lightweight, comfortable, in EWD and algorithms to detect disease onset by monitoring a Warfighter's health state. - Continue the development of vertical flow assay technologies that are rapid, capable of multiplexing, portable, and may result in a faster sample to answer and more sensitive detection level than traditional lateral flow diagnostics. - Continue program to identify biological indicators that predict disease severity, which will lead to the development of a diagnostic that alerts medical personnel that a patient's condition may worsen or require immediate intensive care. - Continue the development of a POC diagnostic platform that can provide the Warfighter pre-symptomatic diagnosis of infection, irrespective of whether the underlying pathogens are viral, bacterial, or parasitic - Initiate the development of a non-invasive prototype platform capable of diagnosing infectious diseases through collection and analysis of an individual's breath. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$6.700 Million) transferred to UN3.</p>	11.182	8.437	-
<p>Title: 3) Battlefield Readiness</p> <p>Description: Provide innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care. Develop field forward medical diagnostics that allow for multiplexed detection of biological and toxin threats. Leverage immunodiagnosics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.</p> <p>FY 2022 Plans:</p>	3.784	4.400	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Complete the development a portable, ultrasensitive immunological diagnostic platform that enables rapid identification and diagnosis of a broader range of threats across the continuum of care, post symptom onset.</p> <p>- Initiate the development of additional panels for infectious disease diagnostic tests on the immunological diagnostic platform.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 Funding (\$5.094 Million) transferred to EN3. Increase due to change in technical parameter.</p>				
<p>Title: 4) Chemical Diagnostics</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional CWAs, including pharmaceutical based agents. Coordinate with the Intelligence Community (IC) to understand the chemical threat space, adapting capabilities to meet the need.</p> <p>FY 2022 Plans:</p> <p>- Complete the research and development of a wearable device that is a continuous sensing platform for DICE, capable of alerting the Warfighter to potential exposure to traditional and nontraditional CWAs.</p> <p>- Initiate efforts that expand the capability of wearable devices from an alert to an FDA-approved diagnostic platform that can detect a chemical threat and allow a physician to diagnose and determine a treatment strategy for exposure to traditional/nontraditional chemical agents.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.914 Million) transferred to UN3.</p>		4.085	4.371	-
<p>Title: 5) Chemical Diagnostics</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional CWAs, including pharmaceutical based agents.</p>		1.973	-	-
<p>Title: 6) Clinical Evaluation</p> <p>Description: Optimize the diagnostic development pathway by incorporating independent testing and evaluation for more informed prototype transition prior to advanced development. Investments in this area allow e evaluation of diagnostic platforms through real world, austere environment testing. This area maintains access to research sites that offer native populations exposed to diseases of interest that would affect the Warfighter in battlefield settings, and provides the ability to acquire novel technologies and provide analytical testing, evaluation, and reach back support for technologies already fielded.</p>		6.004	3.871	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating. - Complete third party testing for bacterial versus viral prototypes. - Initiate test plans for a prototype capable of single molecule-based pathogen identification and assessment of pathogen susceptibility to antimicrobial agents. - Initiate test plans for a wearable sensor capable of detecting exposure to chemical warfare agents. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.914 Million) transferred to UN3.</p>			
<p>Title: 7) Emerging Threats</p> <p>Description: Advance the diagnosis of emerging and/or low prevalence but high threat biological agents leveraging novel technologies. Develop threat agnostic tests based on host biomarkers that identify known or emerging bacterial or viral infections. Characterize markers for antibiotic resistance or susceptibility to identify challenging threats and inform treatment decisions. Improve capabilities to identify diverse biological agents that are not well characterized using molecular or immunodiagnostic approaches.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete work on POC diagnostics to identify AMR microorganisms and perform AST in less than one hour. - Initiate efforts that explore the proteomic expression profiles of bacterial pathogens when they are challenged with antibiotics to characterize regulatory mechanisms of antibiotic resistance. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 Funding (\$2.264 Million) transferred to EN3.</p>	1.134	3.851	-
<p>Title: 8) Emerging Threats</p> <p>Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.</p> <p>FY 2022 Plans:</p>	2.493	3.134	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>- Complete work on POC diagnostics to identify Antimicrobial Resistance (AMR) microorganisms and perform AST in less than one hour.</p> <p>- Continue the development of a universal blood sample preparation platform to be compatible with several diagnostic systems.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.828 Million) transferred to UN3.</p>			
<p>Title: 9) Diagnostic Building Blocks</p> <p>Description: The Diagnostic Building Blocks thrust area lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue efforts that support the advancement of genomics capabilities at USAMRIID. - Initiate novel efforts in artificial intelligence (AI) and ML for designing broader and more specialized assay panels for Chemical and Biological (CB) threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 Funding (\$3.962 Million) transferred to EN3. Increase due to change in technical parameter.</p>	1.303	2.751	-
<p>Title: 10) Diagnostic Building Blocks</p> <p>Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats in days instead of weeks.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete the development of protocols for generating SYMBAs that are sensitive and specific and can be applied to various diagnostic platforms, supporting open-architecture capabilities. - Continue the research and development of CRISPR based solutions for field diagnostics that will provide an ultra-sensitive, cost-effective, and accurate medical diagnostic solution for the Warfighter against unknown biological threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	10.574	5.611	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.786 Million) transferred to UN3.			
<p>Title: 11) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter NTAs and emerging chemical threats to protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability. Successful prophylactics will rapidly detoxify a broad spectrum of compounds of interest (COIs).</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to develop OPNA catalytic scavenger enzymes in support of investigational new drug (IND) submission to the FDA. - Initiate GLP pharmacokinetics, immunogenicity and efficacy of catalytic scavenger enzyme lead candidates in small animals. - Initiate enzyme cGMP manufacturing scale-up. - Hold pre-IND Meeting with FDA to obtain guidance on the regulatory path. - Continue formulation efforts. - Continue enzyme non-cGMP manufacturing scale-up. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.174 Million) transferred to MT3.</p>	9.821	6.742	-
<p>Title: 12) Pharmaceutical Based Agents (PBAs)</p> <p>Description: Focuses on therapeutic and proactive strategies to effectively minimize injuries and/or death resulting from exposure to Pharmaceutical Based Agents (PBAs). This will allow the Warfighter to maintain operational capacity in a chemically contested battlefield scenario. This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment and pretreatment against chemical warfare injury.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of Rapid Opioid Countermeasure System (ROCS) higher concentration Naloxone formulation for use in a multiuse vial format through NDA by FDA. - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. - Assess operational feasibility of employing FDA approved opioid antagonist MCM to provide extended duration of protection. - Continue development of novel therapeutic products to mitigate Opioid-Induced Respiratory Depression (OIRD) to reduce lethality in CWA exposed Warfighters. 	2.019	4.065	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
- Continue studies to assess safety, efficacy, and tolerance of COTS products and dosages for opioid based PBA exposure.				
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.185 Million) transferred to MT3.				
Title: 13) Reactivators of AChE as Therapeutics (ReACT) Description: The Warfighter requires rapid acting medical countermeasures (MCMs) to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation. Efforts in this area are focused on formulation development and pre-clinical studies for potential candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or previously licensed products for new uses in the treatment of chemical warfare casualties. FY 2022 Plans: - Continue to advance pre-clinical development of lead therapeutic candidates. - Continue investigating technologies for delivering therapeutics to the brain. - Continue formulation efforts for lead therapeutic candidates. - Continue in vivo screening for lead therapeutic candidates. - Continue pre-clinical studies of lead reactivators to support future IND filing. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.618 Million) transferred to MT3.		3.904	6.534	-
Title: 14) Bacterial Therapeutics Description: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents. FY 2022 Plans: - Continue multiple efforts to identify and advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward IND and Phase 1 clinical studies. - Utilizing flexible and agile acquisition vehicles, continue to partner with interagency, international, and industry partners to develop nonclinical biodefense efficacy packages for therapeutic assets in advanced development. - Complete non-human primate studies to demonstrate efficacy at humanized doses against anthrax or melioidosis and transition to HHS BARDA. - Complete non-human primate pharmacokinetics studies for one immunomodulatory drug readying the candidate for transition to advanced development and transition to Health & Human Services (HHS) Biomedical Advance Research and Development Authority (BARDA).		13.106	12.618	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue to deliver proof of concept and humanized nonhuman primate efficacy biodefense data packages to interagency joint development programs for transition to HHS BARDA.</p> <p>- File INDs for novel orally-delivered and IV therapeutic for treatment of B. pseudomallei infection. This will support planned Phase I clinical trial.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Program/project funding transferred to another funding line. FY23 funding transferred to MT2. Beginning in FY23, the Viral/Bacterial/Toxin Therapeutics bullets will be consolidated into Biological Warfare Defense Therapeutics.</p>				
<p>Title: 15) Viral Therapeutics</p> <p>Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> <p>FY 2022 Plans:</p> <p>- Continue broad-spectrum, small molecule and monoclonal antibody selection and evaluation in NHP models for multi therapeutic applications.</p> <p>- Transition lead Alphavirus Therapeutics small-molecule candidate to advanced development.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Program/project funding transferred to another funding line. FY23 funding transferred to MT2. Beginning in FY23, the Viral/Bacterial/Toxin Therapeutics bullets will be consolidated into Biological Warfare Defense Therapeutics.</p>		9.417	12.618	-
<p>Title: 16) Toxin Therapeutics</p> <p>Description: Discover and develop therapeutic countermeasures to protect the warfighter against biotoxin threats.</p> <p>FY 2022 Plans:</p> <p>- Continue evaluation of efficacy of repurposed drug for treatment of botulinum neurotoxin (BoNT) B, E or F intoxication in non-human primate animal model.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Program/project funding transferred to another funding line. In FY23 all Bacterial/Viral/Toxin Therapeutics bullets consolidated to new single bullet title Biological Warfare Defense Therapeutics.</p>		0.243	0.250	-
<p>Title: 17) Medical Countermeasures Initiative</p> <p>Description: The Chem Bio Incident Preparedness and Response-Medical Countermeasures Initiative (CBIPR-MCMI) will integrate advances in regulatory science and flexible manufacturing technologies and processes; and develop animal models and drug discovery and evaluation platforms as enablers of the advanced development of CBDP medical countermeasure products.</p>		21.281	21.602	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>These initiatives will lead to the establishment of multi-use platforms and animal models that can be leveraged during a CBRN response to accelerate medical product development and/or regulatory approval as well as reduce overall development costs.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Conduct Phase 1 clinical trial for Venezuelan Equine Encephalitis (VEE) DNA vaccine. - Continue to invest in novel expression systems and expand outer membrane vesicle based bacterial expression platforms for bacterial vaccine candidates. - Invest in novel platform technologies to support rapid medical countermeasure candidate development, including prospective candidate DNA banking, additional cell line development. - Invest in novel expression systems, including rapid manufacturing systems. - Continue to invest in technologies that support regulatory science. - Continue to invest in animal model development to support, test, and evaluate MCMs and the capability to respond to emerging threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$21.928 Million) transferred to EN3</p>			
<p>Title: 18) Bacterial/Viral/Toxin/Broad Spectrum Prophylaxis</p> <p>Description: The ultimate protection of the Warfighter is by pretreating the Warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the Warfighter to work in a less restrictive environment, absent of any personal protective equipment allowing operation at peak performance. Investments in this Program Element supports de-risking of candidates for transition into advanced development and includes: manufacturing process development, pre-clinical studies for lead candidates to allow initiation of clinical work, regulatory science to support clinical initiation, animal model development for FDA animal rule licensure, and Phase 1 clinical trials. Candidates transition into advanced development once the Phase 1 clinical trial is complete.</p> <p>FY 2022 Plans: Bacterial:</p> <ul style="list-style-type: none"> - Complete non-clinical safety and efficacy studies for Tularemia prophylaxis with the ClpB vaccine for advancement to clinical Phase 1. - Complete non-clinical safety and efficacy studies with the Tularemia Fn-IgID vaccine for advancement to clinical Phase 1. - Continue manufacturing and nonclinical development of next generation plague and tularemia monoclonal antibody cocktail. - Complete non-clinical safety and efficacy studies on a live attenuated plague vaccine candidate for advancement to clinical Phase 1. 	31.839	31.736	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>- Complete the proof of efficacy animal testing for the anthrax CPS conjugate vaccine candidate for advancement to clinical Phase 1.</p> <p>- Complete Q Fever human seroprevalence study to determine what percentage of Warfighter would be eligible to receive QVax vaccine. Results will be transitioned to advanced development to support their evaluation of QVax for further advanced development.</p> <p>Viral:</p> <p>- Continue assay qualification and validation for Ebola virus, Marburg virus, and alphavirus vaccines.</p> <p>- Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines</p> <p>- Complete evaluation of rVSV Ebola vaccine duration of protection assessment to support CONOPs development for Ebola Vaccine use by the Services.</p> <p>- Continue evaluation and mitigation studies of Filovirus aerosol pathology.</p> <p>- Initiate animal efficacy testing against panel of respiratory viruses of broad spectrum epithelial nanosponge technology.</p> <p>Toxins:</p> <p>- Complete transition of the multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin to advanced development BoNT mAb program at JPEO-CBRND following the completion of the Phase 1 clinical trial.</p> <p>- Initiate large animal efficacy testing of mAb cocktail for protection against Palytoxin.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$27.632 Million) transferred to PT3. Starting in FY23, Viral/Bacterial/Toxin Therapeutic bullets will be consolidated into a single new bullet title Biological Warfare Defense Therapeutic.</p>			
Accomplishments/Planned Programs Subtotals	134.162	137.691	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• EN3: <i>Enabling Investments (ATD)</i>	0.000	0.000	42.590	-	42.590	43.197	43.198	44.449	44.449	Continuing	Continuing
• MT3: <i>Mitigate (ATD)</i>	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing
• PT3: <i>Protect (ATD)</i>	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing
• UN3: <i>Understand (ATD)</i>	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing
• EN4: <i>Enabling Investments (ACD&P)</i>	0.000	0.000	8.781	-	8.781	9.172	9.179	9.392	9.440	Continuing	Continuing

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TM3 / Techbase Medical Defense (ATD)
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• MB4: <i>Medical Biological Defense (ACD&P)</i>	42.993	47.351	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	90.344
• PT4: <i>Protect (ACD&P)</i>	0.000	0.000	203.689	-	203.689	183.220	139.375	113.754	105.176	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TT3 / Technology Transition (ATD)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
TT3: Technology Transition (ATD)	-	10.341	8.787	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	19.128
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Project TT3 validates high-risk/high-payoff technologies, concepts-of-operations, and a Joint Combat Developer concept development and experimentation process to significantly improve Warfighter capabilities in preparation for transition of mature chemical and biological (CB) defense technologies to advanced development programs. This project addresses the three primary chemical and biological defense thrust areas of Assess, Protect, and Mitigate with an emphasis on Integrated Early Warning (IEW) and Integrated Layered Defense (ILD). IEW is conducted through a coordinated program approach focused on layering chemical and biological detection technologies and integrating CB threat indicators, providing a combination of awareness and understanding that facilitates effective decision making so the force can continue military operations and achieve mission success in a CBRN environment. The ILD achieves solutions for capability gaps across medical and non-medical commodity areas to enable warfighter survival and rapid recovery in a CBRN environment. In FY2023, the CBDP RDT&E Projects have been restructured to align to the CBDP portfolio. TT3 thrust areas in FY2022 progress to the Enabling Investments (EN3) portfolio. This restructuring is intended to provide standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

- Programs that offer the opportunity to identify and efficiently mature emerging technologies, reduce risks, and finalize engineering and integration efforts.
- Programs that seek to demonstrate the potential for enhanced military operational capability and/or cost effectiveness. Upon conclusion of the technical and operational demonstrations, the user or sponsor provides a determination of the military utility and operational impact of the technology and capability demonstrated. Successfully demonstrated technologies with proven military utility can remain in place for future extended user evaluations, accepted into the advanced stages of the formal acquisition process, proceed directly into limited or full- scale production or be returned to the technical base for further development.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Advanced Technology Demonstration	5.724	5.640	-
Description: Advanced Technology Demonstrations (ATDs) facilitate Warfighters and other operational stakeholders' participation in field demonstrations that evaluate integrated technologies or prototype systems with demonstrated technical performance in high fidelity and realistic operating environments. Building on the technology concepts and user assessments thrust areas conducted earlier in the technology maturation process, feedback from the Warfighters during ATDs ensures that these technologies are operationally relevant, value added, and can be matured and potentially transitioned in a timely and effective manner to S&T Managers or transition partners for advanced development and employment across the spectrum of Joint Force actions in a CBRN Defense Environment. In some cases, ATD residuals are left with ATD operating units for extended user			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 3		R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)		Project (Number/Name) TT3 / Technology Transition (ATD)
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>evaluations which provides additional real world data to technology developers. ATD outcomes area designed to enhance transition of cutting edge CBRN technologies and mitigate transition risk by demonstrating operational utility and initial Technics, Tactics and Procedures.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue CMWD Integrated Tactical Information Recon System (CITRIS): heads up display CWMD Common Tactical Picture to support end user CWMD tactical situational awareness. - Continue Integrated Threat Response Advanced Technology Demonstration (ITR ATD) Demonstrate whole of force (IEW and ILD) Warfighter operations in a CBRN Environment. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$6.195 Million) transferred to EN3.</p>				
<p>Title: 2) Technology Concept</p> <p>Description: Initiatives to validate technology requirements and scope future S&T programs with Warfighter stakeholders, including Combat Developers and Service representatives. Results from these experiments shape Operating Concepts, doctrine, and materiel systems requirements for the future Joint Force and inform technology developers about potential Warfighter utility of emerging technologies and technology concepts for subsequent portfolio investment. Activities in this area focus on Surveys, User Groups, Table Top Exercises (TTXs), and practical demonstration or User feedback workshops to develop Use Cases, desired operational capabilities, key attributes and explore Concepts of Employment to assess feasibility/utility of emerging technologies.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Conduct three to five concept studies including LMIT, LMOC, Leave and Forget Sensor Concept. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.296 Million) transferred to EN3.</p>		2.242	1.296	-
<p>Title: 3) User Assessment</p> <p>Description: User Assessments examine maturing technologies and provide opportunities for early Warfighter input into the form, fit, and function of maturing S&T prototypes and technologies; and as appropriate, assess them within a simulated operational environment. The assessments serve as baselines for future Advanced Technology Demonstration (ATD) programs, and drive S&T gap analysis for key customers and partners. User assessments are characterized by TTXs, Early User Assessments, Technical demonstrations and field experiments that provide candid feedback focused on applicability, utility and recommended</p>		2.375	1.851	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)	Project (Number/Name) TT3 / Technology Transition (ATD)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
improvements while exploring system limitations, vulnerabilities and technology tradeoff analyses of innovative technologies in a non-attributional environment.			
<i>FY 2022 Plans:</i> - Continue the annual CB Operational Analysis (CBOA) event.			
<i>FY 2022 to FY 2023 Increase/Decrease Statement:</i> Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.851 Million) transferred to EN3.			
Accomplishments/Planned Programs Subtotals	10.341	8.787	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• TT4: Technology Transition (ACD&P)	0.577	0.866	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	1.443

Remarks

D. Acquisition Strategy

N/A