Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Chemical and Biological Defense Program											Date: February 2016	
Appropriation/Budget Activity 0400: *Research, Development, Test & Evaluation, Defense-Wide* / BA 3: *Advanced Technology Development (ATD)*					R-1 Program Element (Number/Name) PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*							
COST ($ in Millions)	**Prior Years**	**FY 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	-	147.141	140.094	127.941	-	127.941	142.815	140.382	143.221	147.091	Continuing	Continuing
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	-	17.362	16.062	19.109	-	19.109	18.343	17.899	18.035	18.038	Continuing	Continuing
NT3: *TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)*	-	21.534	22.948	17.173	-	17.173	19.885	19.378	19.541	19.544	Continuing	Continuing
TM3: *TECHBASE MED DEFENSE (ATD)*	-	102.610	93.725	83.838	-	83.838	93.720	92.727	94.495	98.357	Continuing	Continuing
TT3: *TECHBASE TECHNOLOGY TRANSITION*	-	5.635	7.359	7.821	-	7.821	10.867	10.378	11.150	11.152	Continuing	Continuing

A. Mission Description and Budget Item Justification

Demonstrates technologies supporting transition to advanced component development. This includes physical capabilities which cover biological and chemical detection, situational awareness and effects modeling, and protection and hazard mitigation. Other major efforts support enhanced chemical detection capabilities for aerosols and non-traditional agents, expanded capabilities for biosurveillance in pathogen detection and diagnosis, and pretreatments and therapeutics against a broader set of chemical and biological agents. Medical capabilities (pretreatments, therapeutics, diagnostics capabilities, and drug manufacturing and regulatory science technologies), include capabilities against non-traditional agents.

In the physical sciences area, Project CB3 focuses on demonstrations of CB defense technologies, including biological detection, chemical detection, information system technology for hazard prediction and systems performance, and protection, and decontamination. The Project continues to pursue solutions against traditional agents.

All non-traditional agent (NTA)-dedicated research (both medical and non-medical) is consolidated in Project NT3. This Project includes NTA chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

The medical program in Project TM3, aims to produce biological diagnostic assays and reagents, diagnostic device platforms, pretreatments and therapeutics for bacterial, viral, and toxin threats as well as for chemical threats, and medical devices, as countermeasures for CBR threat agents. Specific areas of medical investigation include: prophylaxis, pretreatment, antidotes and therapeutics, personnel and patient decontamination, and medical management of casualties.

Project TT3, Techbase Technology Transition, pursues efforts to enhance military operational capability, concepts of operation, WMD elimination, and hazard mitigation following a biological warfare or chemical warfare attack.

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The PE is dedicated to conducting proof-of-principle field demonstrations, and testing system-specific technologies to meet specific military needs. Work conducted under this PE will transition to and will provide risk reduction for PE 0603884BP/PE 0604384BP activities.

B. Program Change Summary ($ in Millions)	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	155.374	140.094	145.877	-	145.877
Current President's Budget	147.141	140.094	127.941	-	127.941
Total Adjustments	-8.233	0.000	-17.936	-	-17.936
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	-			
• Congressional Directed Transfers	0.000	-			
• Reprogrammings	-6.086	-			
• SBIR/STTR Transfer	-2.147	-			
• Other Adjustments	0.000	-	-17.936	-	-17.936

Change Summary Explanation

Funding: N/A

Schedule: N/A

Technical: N/A

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COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
CB3: *CHEMICAL BIOLOGICAL DEFENSE (ATD)*	-	17.362	16.062	19.109	-	19.109	18.343	17.899	18.035	18.038	Continuing	Continuing

A. Mission Description and Budget Item Justification

Project CB3 develops technology advancements for joint service application in the area of information systems and modeling and simulation technologies. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: 1) Expeditionary Collective Protection	0.790	-	0.566
Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters. ***FY 2015 Accomplishments:*** Completed the fabrication and laboratory verification of the satellite cartridge Residual Life Indicator (RLI). RLI simulates the carbon bed in a CBRN collective protection filter. Overall design and efficacy of preliminary prototypes were assessed on Naval ships. In prototype evaluation, RLI cartridge system was placed in filter plenum and exposed to field environment, removed along with lots of carbon from filters in plenum, and subsequently subjected to breakthrough tests to initially assess correlation of RLI performance to carbon in the filter plenum. Information from initial field assessment was used to optimize cartridge design. ***FY 2017 Plans:*** Assess performance of optimized RLI satellite filter cartridge. Verify the RLI performance is correlated to that of the carbon bed in a CBRN collective protection filter. Establish the filter bed performance is effectively correlated with the RLI and extended with Guard Bed.			
Title: 2) Material Contamination Mitigation	0.822	2.056	2.230
Description: Demonstration of non-traditional or novel decontamination technologies and approaches which gain significantly improved effectiveness by complementary application. ***FY 2015 Accomplishments:*** Initiated non-aqueous sorbent decontaminant formulation effort for immediate decontamination to leverage emerging technologies and data that demonstrates significantly greater efficacy if decontamination process is initiated within the first hour. Transitioned new acceptance criteria for chemical agent resistant coating (CARC) acceptance to the CARC commodity manager after inter-laboratory validation. Initiated technology enhancement effort for Contamination Indicator/Decontamination Assurance			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Spray (CIDAS) to advanced development. Completed technology assessment and transitioned data on mustard (HD) CIDAS formulation in support of CIDAS program of record. Initiated the radiological/nuclear decontamination/hazard mitigation effort to define scope of challenges and outline concept of operations. Transitioned Joint Biological Agent Decontamination System (JBADS) hazard mitigation technology data related to complex spores to advanced development. Continued S&T efforts to complete the formulation component of dial-a-decon. ***FY 2016 Plans:*** Complete maturation of formulation component of Dial-a-Decon project. Conduct a technology readiness assessment and transition data package. Continue development of the Dial-a-Decon brassboard to enhance efficacy by modifying dissemination of formulations. Initiate development of the next generation of hazard mitigation technologies that include integration of multiple systems to achieve efficacy goals. Conduct a field trial of Wide Area Decon technologies. Continue responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. ***FY 2017 Plans:*** Transition sorbent decontaminant formulation effort to advanced development for immediate decontamination, focusing on efficacy testing and final formulation compatibility testing. Initiate room temperature ionic liquid decontaminant effort to address sensitive equipment decontaminant need (enzyme and catalytic) projects, specifically focusing on efficacy testing and formulation. Continue application of data gathered from surface science investigations to inform design to initiate development of the next generation of hazard mitigation technologies that include integration of multiple systems to achieve efficacy goals. Continue enhanced CB survivability and responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. Demonstrate the wide-area decontamination hazard mitigation effort, which focuses on biological spore decontamination in a representative outdoor environment.			
Title: 3) Percutaneous Protection ***Description:*** Study and assessment of percutaneous protective technologies. ***FY 2015 Accomplishments:*** Completed demonstration of ensemble concepts that use protective fabric technologies developed during the previous year's programs. Completed whole-system man-in simulant testing and manikin live agent testing of selected ensembles. Transitioned data from Government and industry lightweight, lower thermal burden materials to the Uniform Integrated Protective Ensemble (UIPE) program. ***FY 2016 Plans:***	1.595	1.241	0.453

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Investigate engineering and manufacturing limitations for the production and system integration of multifunctional materials. Develop system integration approaches for incorporation of those materials in protective garments. ***FY 2017 Plans:*** Develop and demonstrate fully integrated ensembles for full-spectrum hazards that support tactical operations for all services. Develop ensembles that include novel garment designs that integrate with body armor, helmet, cooling systems, breathing apparatuses, and combat loads that are scalable to mission demands which will fill a broad set of existing capability gaps for many diverse DoD units.			
Title: 4) Personnel Contamination Mitigation ***Description:*** Develop new technologies to alleviate the risk associated with contaminated human remains and personnel effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents to support warfighter operations, including homeland defense mission. ***FY 2015 Accomplishments:*** Initiated effort to explore enhancement of operational concepts related to mitigation of hazards related to human remains and personnel effects. ***FY 2017 Plans:*** Continue to develop new technologies to alleviate the risk associated with contaminated human remains and personnel effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents to support warfighter operations, including the homeland defense mission. This effort also leverages the related BA2 development effort started in FY16.	0.139	-	0.085
Title: 5) Respiratory and Ocular Protection ***Description:*** Demonstration of novel filtration media into a lightweight, low-profile, and low-burden individual protective filter, which has enhanced performance against a broader range of challenges that includes toxic industrial chemicals. ***FY 2015 Accomplishments:*** Developed several promising respiratory and ocular protection technologies including a dual cavity pressurization of a full-facepiece respirator that isolates the nose cup for respiration, dynamic response pressure sensors to evaluate the real time performance of the mask seal or overall mask protection, and Closed Circuit-SCBA systems to allow for adaptable tactical respiratory protection systems with lower logistical burden. Emerging technologies for oxygen (O2) storage, carbon dioxide (CO2) removal, and process cooling of respirable air offer the potential for significant system weight reduction. ***FY 2016 Plans:***	1.037	0.807	0.905

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Develop, fabricate, and evaluate hybrid system technology prototypes. Transition a synthetic nano-structured material focused on toxic industrial chemical removal, including ammonia. ***FY 2017 Plans:*** Continue integration of respirator component technologies into a full-spectrum protection system which provides scalable protection. Research and development efforts will include nanotechnologies, anti-fogging materials, dynamic response breathing, oxygen storage and CO2 scrubbing.			
Title: 6) Biosurveillance (BSV) ***Description:*** Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, impact and biological threat assessment. Contribute to the development of global, near real-time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into disease modeling, medical resource estimation and decision support tools. ***FY 2017 Plans:*** Continue biosurveillance analytic evaluations and various analytic capability development, including sequence data sharing, disease reemergence analytics, and pathogen spread visualizations in support of the Joint Program Management Office - Information Systems (JPM-IS). These efforts were developed in FY16 under BA3 TM3 Biological Diagnostics.	-	-	2.643
Title: 7) Detection ***Description:*** Focuses on the detection and identification of chemical and biological threats in near real-time at a distance from the detector. Future programs focus on the improvement of algorithms, excitation sources, and detector elements to increase range, reduce false positives, increase sensitivity, and reduce cost. ***FY 2015 Accomplishments:*** Continue processes of validating ground truth systems for detection technologies (genomic and proteomic technology) field assessments to lead into the initiation of sequence based comprehensive identification and characterization platform development for field forward capability. ***FY 2016 Plans:*** Continue sequence based comprehensive identification and characterization platform development for field forward capability. ***FY 2017 Plans:*** Continue handheld sequencer based platforms for comprehensive identification and characterization for field forward capabilities.	3.863	4.159	4.066
Title: 8) Hazard Prediction	4.470	1.379	2.309

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Description: Improve battlespace awareness by accurately predicting hazardous material releases, atmospheric transport and dispersion, and resulting human effects. Develop predictive capability for the source term of releases of chemical, biological, and industrial materials. ***FY 2015 Accomplishments:*** Continued implementation of new numerical schemes and performance optimization for transport and dispersion models. Continued enhancement of high-fidelity urban transport and dispersion. Continued configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for Hazard Prediction and Assessment Capability/Joint Effects Model (HPAC/JEM). Completed implementation and testing of new numerical schemes for future establishment of 64-bit/multi-core-capable models, improving model speed and performance by increasing addressable memory and improving parallel processing. ***FY 2016 Plans:*** Continue implementation of new numerical schemes and performance optimization for transport and dispersion models. Continue enhancement of high-fidelity urban transport and dispersion. Continue configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for HPAC/JEM. Continue next-generation development of missile intercept/functioning missile effects model. ***FY 2017 Plans:*** Continue implementation of new numerical schemes and performance optimization for transport and dispersion models. Continue enhancement of high-fidelity urban transport and dispersion. Continue configuration management of science and technology prototype to establish upgraded capabilities listed as valid requirements for HPAC/JEM.			
Title: 9) Data Analysis ***Description:*** Develop chemical, biological, radiological and nuclear data-sharing capabilities. Develop chapters of the Chemical and Biological Warfare Agent Effects Manual Number 1 (CB-1), an authoritative source capturing analytical methods for evaluating the effects of CB warfare agents on equipment, personnel, and operations. Create a framework for implementing CB-1 and provide CBRN defense community access to CB-1. ***FY 2015 Accomplishments:*** Initiated development of a framework for the Chemical and Biological Agent Effects Manual Number 1 (CB-1) within a test version of the Defense Threat Reduction Information Analysis Center (DTRIAC) Next Gen Scientific and Technical Information Archival and Retrieval System (STARS). Began to develop initial chapters of CB-1. ***FY 2016 Plans:***	0.348	3.722	1.416

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Implement the Chemical and Biological Agent Effects Manual Number 1 (CB-1) on the DTRIAC STARS. ***FY 2017 Plans:*** Continue to implement the Chemical and Biological Agent Effects Manual Number 1 (CB-1) on DTRIAC STARS. Provide CBRN defense community access to CB-1.			
Title: 10) Operational Effects ***Description:*** Develop decision support tools and information management capabilities for planning and real-time analysis to determine and assess operational effects, risks, and overall impacts of CBRN incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management. ***FY 2015 Accomplishments:*** Continued system performance model integration with advanced development programs. Completed second generation system performance model for multiple decontamination systems to evaluate concepts and methodologies that predict the technology efficacy and hazards for a range of agents, materials, decontaminants, and environmental conditions. Produced a risk assessment tool in support of the decision-makers choice using the necessary source terms. Initiated operational effects research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements setting. ***FY 2016 Plans:*** Continue operational effects research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements setting. ***FY 2017 Plans:*** Continue system performance model integration and advanced development for program-wide exploitation for collective and individual protection and contamination avoidance. Continue operational effects research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements settings.	4.298	2.384	4.436
Title: 11) SBIR/STTR ***FY 2016 Plans:*** SBIR/STTR - FY16 - Small Business Innovative Research.	-	0.314	-
Accomplishments/Planned Programs Subtotals	17.362	16.062	19.109

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program			Date: February 2016
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C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• CA4: *CONTAMINATION AVOIDANCE (ACD&P)*	39.930	60.192	42.308	-	42.308	8.238	9.679	12.802	17.381	Continuing	Continuing
• DE4: *DECONTAMINATION SYSTEMS (ACD&P)*	2.051	1.594	0.500	-	0.500	2.500	5.500	12.000	12.500	Continuing	Continuing
• IS4: *INFORMATION SYSTEMS (ACD&P)*	7.585	7.464	5.928	-	5.928	6.187	1.451	0.870	0.783	Continuing	Continuing
• TE4: *TEST & EVALUATION (ACD&P)*	10.913	17.371	14.887	-	14.887	14.823	23.458	14.017	14.991	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
NT3: *TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)*	-	21.534	22.948	17.173	-	17.173	19.885	19.378	19.541	19.544	Continuing	Continuing

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. Efforts in this project 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. 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 transitions them to Budget Activities 4 and 5.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: 1) Diagnostics - Medical	0.571	0.695	-
Description: Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to non-traditional agents in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as, laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker. NOTE: Starting in FY17, program will be accomplished in TM3/Diagnostics. ***FY 2015 Accomplishments:*** Continued development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Continued transition method development for identification and validation of NTAs in clinical samples to the Laboratory Response Network. ***FY 2016 Plans:*** Continue development of mature technologies that can quickly diagnose pre-symptomatic NTA exposure. Continue transition method development for identification and validation of NTAs in clinical samples to the Laboratory Response Network.			
Title: 2) Expeditionary Collective Protection	0.335	-	-
Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters.			

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
FY 2015 Accomplishments: Designed and evaluated pre filter to extend life of collective protection systems. Overall design and efficacy of preliminary prototypes were assessed on Naval ships. In prototype evaluation, Guard Bed was placed in filter and exposed to field environment, removed along with lots of carbon from filters in plenum, and subsequently subjected to breakthrough tests to initially assess extension of filter carbon life. Information from initial field assessment was used to optimize Guard Bed composition and design.			
Title: 3) Material Contamination Mitigation ***Description:*** Study and assessment of decontamination technologies. ***FY 2015 Accomplishments:*** Continued to assess performance and unique aspects of full spectrum of NTAs and developed technologies to optimize performance against NTAs. ***FY 2016 Plans:*** Continue integration of a Point-of-Use decontaminant formulation system with optimized methods for delivery matching the agent, surface and environmental conditions, and optimized application method. Construct a multi-dimensional "Decontamination Performance Region Map" that will facilitate Point-of-Use decontaminant formulation in the field. Continue development of the Dial-a-Decon brassboard to enhance NTA efficacy by modifying dissemination of formulations and complete an assessment of Dial-a-Decon formulas. Integrate NTAs into the continuing responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. ***FY 2017 Plans:*** Continue integration of a Government owned decontaminant formulation system, specifically addressing other classes of emerging threats. Integrate NTAs into the continuing responsive coatings projects to enhance decontaminability as part of the systems approach to achieving efficacy goals. Complete NTA efficacy testing for primary and other emerging threat NTAs to support the transition of the sorbent decontamination formulation effort. Examine room temperature ionic liquid decontaminant efficacy against representative agents from three categories of NTAs.	0.385	2.298	1.585
Title: 4) Personnel Contamination Mitigation ***Description:*** Develop new technologies to alleviate the risk associated with contaminated human remains and personnel effects (materials) exposed to and contaminated by chemical agents by neutralizing and/or physically removing the residual chemical agents. ***FY 2015 Accomplishments:***	0.154	0.058	0.623

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Initiated human remains storage testing to determine how the hazards associated with contaminated human remains are altered by the normal and extended storage conditions, including storage effects on NTAs. ***FY 2016 Plans:*** Explore combinations of complementary technologies to reduce the contamination hazard faster with less outside support and develop revolutionary prototype systems that sense, respond, and signal contamination. ***FY 2017 Plans:*** Continue exploring combinations of complementary technologies to reduce the NTA contamination hazard faster with less outside support and develop revolutionary prototype systems that sense, respond, and signal contamination to support warfighter operations, including homeland defense mission; specifically, advancing formulation options and concepts of operations that include efficacy testing for multiple classes of NTAs.			
Title: 5) Respiratory and Ocular Protection ***Description:*** Development and analysis of design alternatives for chemical and biological air-purifying respirators to provide enhanced protection with lower physiological burden and improved interface with mission equipment. ***FY 2015 Accomplishments:*** Continued to investigate performance limitations current and developmental of respiratory protection systems against NTA challenges. ***FY 2017 Plans:*** Continued to investigate performance limitations current and developmental of respiratory protection systems against NTA challenges and investigate counter-measures to these specific limitations.	0.335	-	0.226
Title: 6) Pretreatments - Medical ***Description:*** Develop pretreatments and prophylactics that provide protection against NTAs and emerging chemical threats. Prophylactic bioscavengers should rapidly bind and detoxify a broad spectrum of compounds of interest (COIs). ***FY 2015 Accomplishments:*** Continued efforts to investigate the feasibility of alternative delivery methods of bioscavengers to afford protection against COIs. Continued to assess an alternate manufacturing process for recombinant butyrylcholinesterase (rBuChE). Contributed to medical countermeasures (MCM) assay efforts at the Absorption, Distribution, Metabolism, Excretion and Toxicity (ADMET) Center of Excellence (CoE). ***FY 2016 Plans:***	6.693	7.621	2.129

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Continue efforts to demonstrate proof-of-concept for IM and pulmonary delivery of a stoichiometric bioscavenger. Continue contributing to alternate manufacturing processes for rBuChE. Demonstrate impact ADMET Research Center of Excellence across multiple medical countermeasure product development efforts. ***FY 2017 Plans:*** Continue studies to advance recombinant bioscavenger MCM through established animal models and pre-IND efforts.			
Title: 7) Therapeutics - Medical ***Description:*** Efforts in this area support the confirmation of mechanisms of action for NTAs and emerging chemical threats by probable routes of field exposure and seek to refine standard experimental routes in order to identify/assess targets for therapeutic development. Physiological parameters and pathological assessments will be used to establish the general mode and mechanisms of toxicity required for therapeutic development. ***FY 2015 Accomplishments:*** Continued to investigate the development of technology to facilitate delivery of therapeutics to the brain. Refined small animal models to support Food and Drug Administration (FDA) licensure. ***FY 2016 Plans:*** Continue support of enabling technology to facilitate delivery of therapeutic regimen to the brain. Continue to refine and validate small animal models to support FDA licensure. ***FY 2017 Plans:*** Continue support of enabling technology to facilitate delivery of therapeutics to the brain. Continue to validate small animal models to support FDA licensure of therapeutics used in the treatment of NTA exposures.	2.274	2.146	1.217
Title: 8) Detection ***Description:*** Detection NTA: Focuses on technologies to provide NTA detection capabilities. ***FY 2015 Accomplishments:*** Continued the development of test methodology to validate signatures for chemical aerosol threat materials, including detection characterization efforts for current and emerging threats at laboratories with chemical surety programs, integrating these validated signatures for platforms that are in development for NGCD. ***FY 2016 Plans:***	8.955	8.669	10.351

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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Continue integration studies for Next Generation Chemical Detector (NGCD) based on Micro Electro-Mechanical Systems components for Gas Chromatography and Mass Spectrometry. Continue the development of test methodology to validate signatures for chemical aerosol threat materials. Initiate the transfer of validated signatures into the NGCD. ***FY 2017 Plans:*** Complete integration studies and prototype delivery for transition to NGCD based on Micro Electro-Mechanical Systems components for Gas Chromatography and Mass Spectrometry.			
Title: 9) Modeling & Simulation ***Description:*** This effort develops NTA technology advancements for joint service application in the area of information systems and modeling and simulation technologies. These activities will speed maturation of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. Information systems advanced technology focuses on areas of advanced warning and reporting, hazard prediction and assessment, simulation analysis and planning, and systems performance modeling. ***FY 2015 Accomplishments:*** Completed analysis of NTA simulant testing. ***FY 2016 Plans:*** Continue sensitivity and validation studies on NTA source term models and update and expand NTA databases. ***FY 2017 Plans:*** Continue sensitivity and validation studies on NTA source term models and update and expand NTA databases.	0.239	0.235	0.240
Title: 10) Percutaneous Protection ***Description:*** Study and assessment of percutaneous protective technologies. ***FY 2015 Accomplishments:*** Assessed and optimized technologies to improve whole system performance against NTAs through NSRDEC resulting in an expanded knowledge base for NTA protection. Transitioned technologies to the Uniform Integrated Protective Ensemble (UIPE) program.	0.913	-	-
Title: 11) Test & Evaluation ***Description:*** Develops test and evaluation technologies and processes in support of NTA activities. ***FY 2015 Accomplishments:***	0.680	0.775	0.802

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** NT3 / *TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Continued further prioritized select agent testing. ***FY 2016 Plans:*** Continue methodology and protocol development to support the evaluation of Next Generation Chemical Detector technologies. ***FY 2017 Plans:*** Initiate rapid prototyping and evaluation of chemical detection platforms.			
Title: 12) SBIR/STTR ***FY 2016 Plans:*** SBIR/STTR - FY16 - Small Business Innovative Research.	-	0.451	-
Accomplishments/Planned Programs Subtotals	21.534	22.948	17.173

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• CA4: *CONTAMINATION AVOIDANCE (ACD&P)*	39.930	60.192	42.308	-	42.308	8.238	9.679	12.802	17.381	Continuing	Continuing
• DE4: *DECONTAMINATION SYSTEMS (ACD&P)*	2.051	1.594	0.500	-	0.500	2.500	5.500	12.000	12.500	Continuing	Continuing
• IP4: *INDIVIDUAL PROTECTION (ACD&P)*	6.253	4.217	3.235	-	3.235	0.000	0.000	0.500	3.500	Continuing	Continuing
• MC4: *MEDICAL CHEMICAL DEFENSE (ACD&P)*	0.000	0.000	5.681	-	5.681	0.000	0.000	0.000	0.000	0	5.681
• TE4: *TEST & EVALUATION (ACD&P)*	10.913	17.371	14.887	-	14.887	14.823	23.458	14.017	14.991	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program			Date: February 2016
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	Project (Number/Name) TM3 / *TECHBASE MED DEFENSE (ATD)*	

COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
TM3: *TECHBASE MED DEFENSE (ATD)*	-	102.610	93.725	83.838	-	83.838	93.720	92.727	94.495	98.357	Continuing	Continuing

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. 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. In addition this project supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants and therapeutic drugs against identified and emerging chemical warfare threat agents. Entry of candidate vaccines, therapeutics, and diagnostic technologies into advanced development is facilitated by the development of technical data packages that support the Food and Drug Administration (FDA) Investigational New Drug (IND) processes, DoD acquisition regulations, and the oversight of early phase clinical trials in accordance with FDA guidelines. This project also supports the advanced development of medical countermeasures to protect the Warfighter against radiological/nuclear exposure.

The Medical Countermeasures Initiative (MCMI) was established to coordinate inter-related advanced development and flexible manufacturing capabilities, providing a dedicated, cost-effective, reliable, and sustainable MCM process that meets the Warfighter and national security needs. MCMI efforts within science and technology (S&T) are concentrated in advancing two areas: 1) regulatory science and 2) flexible manufacturing technologies and processes for MCMs. Efforts conducted in these areas are enablers supporting the DoD Medical Countermeasures Advanced Development and Manufacturing (MCM-ADM) capability.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: 1) Assays and Reagents	18.205	11.335	16.488
Description: Development and verification of rapid, sensitive, and specific tests for the identification of Biological Warfare Agents (BWAs) and their expressed pathogens and toxins in clinical specimens from Warfighters for the diagnosis of exposure/infection. Discovery of host biomarkers generated in response to exposure to biological threat agents.			
FY 2015 Accomplishments: Continued to mature thermostable reagents for use in austere biosurveillance environments. Continued to collaborate with the CDC to improve diagnostic and surveillance capabilities needed to counter traditional, engineered, emerging and biological threats. Continued development and transition signature analysis and assay/device for strain identification and genotyping of Burkholderia pseudomallei and CCHF virus. Continued development of mass spectrometry protocol capable of identifying HHA false positive triggers on multiple toxin lateral flow assays. Transitioned sequencing and analysis of B. pseudomallei genomes			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TM3 / *TECHBASE MED DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
and near neighbor genomes to the Critical Reagents Program. Began Phase II of Republic of Korea (ROK) Project Agreement to expand into pathogen discovery capabilities. ***FY 2016 Plans:*** Validate the performance of 50 multi-plex assays utilizing the MAGPIX format (multiplexing platform capable of performing qualitative and quantitative analysis) for the detection of Burkholderia pseudomallei and its near neighbors. Continue Phase II of ROK Project Agreement. ***FY 2017 Plans:*** Continue the development and production of thermostable reagents. Continue the development of assays and technologies for biothreat agent detection and characterization. Continue verification and testing performance of biomarker assays and reagents for point-of-need diagnostic platforms. Continue to optimize pipelines to improve unbiased pathogen discovery and/or detection in clinical and environmental samples. Continue optimization and enhancement of updated bioinformatics platform to support genomic and clinical informatics. Evaluate optimization and enhancement of updated bioinformatics platform in the field including efforts in the ROK.			
Title: 2) Bacterial Therapeutics ***Description:*** Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents. ***FY 2015 Accomplishments:*** Evaluated FDA approved compounds for efficacy in non-human primate models against aerosolized challenge of Bacillus anthracis. Developed novel ribosome inhibitors as therapeutics for priority bacterial pathogens. Continued non-clinical research required to submit IND applications to the FDA for additional products. Continued non-clinical work utilizing the Animal Rule for the submission of Supplemental New Drug Applications (sNDAs), reducing the focus to novel topoisomerase inhibitors and addressing a limited number of priority pathogens. ***FY 2016 Plans:*** Conduct evaluation of an FDA approved compound for efficacy in pivotal GLP non-human primate studies against an aerosolized challenge of F. tularensis in support of submission of a sNDA under the Animal Rule. Down select between novel ribosome inhibitors and a novel topoisomerase inhibitor as therapeutics for priority bacterial pathogens. Continue non-clinical research required to submit IND applications to the FDA for additional products. Continue supportive pivotal GLP studies to further the advancement of both novel and approved therapeutics for limited priority pathogen indications under the Animal Rule. ***FY 2017 Plans:***	10.869	10.198	16.033

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TM3 / *TECHBASE MED DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Expand evaluation of FDA approved compounds for efficacy in pivotal GLP non-human primate models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a sNDA under the Animal Rule. Combinatorial testing of FDA approved drugs for efficacy and decreased development of resistance. Submission of an IND to the FDA for a small molecule inhibitor for the treatment of Burkholderia pseudomallei. Continue non-clinical research to advance additional therapeutic products with the goal of submission of an IND to the FDA. Work previously funded under TM3/ MCMI to evaluate and develop platforms for enablers of the advanced development of medical countermeasures will be continued here.			
Title: 3) Bacterial/Toxin Vaccines ***Description:*** Evaluate the best single agent bacterial and toxin vaccines for effectiveness against aerosol challenge in large animal models. ***FY 2015 Accomplishments:*** Completed Phase 1 clinical trial to assess safety, tolerability and immunogenicity of RVEc, a ricin toxin vaccine. Down-selected to ricin toxin vaccine candidate, RVEc, developed at USAMRIID and completed passive transfer studies in mice. Continued with the advanced developer to fulfill S&T needs in support of the ricin vaccine transition. ***FY 2016 Plans:*** Complete transition ricin vaccine. Utilize ongoing clinical work to generate monoclonal antibodies against ricin toxin. Demonstrate proof-of-concept efficacy for lead Tularemia Vaccine in nonhuman primate model. Continue development of a monoclonal antibody-based pretreatment against botulinum neurotoxin. Explore technology transfer of manufacturing to a suitable long-term manufacturing partner. Develop and evaluate bridging strategies for interim fielding capability readiness. ***FY 2017 Plans:*** Conduct feasibility studies to assess efficacy of lead type A Francisella tularensis (Tularemia) vaccine prototypes. Demonstrate feasibility and efficacy of combinations of vaccines designed with different antigens to protect against aerosolized, engineered pathogens in animal models. Assess feasibility of prototype oral Bacillus anthracis (anthrax) vaccines in small animal model. Complete tri-target and penta-target formulations of monoclonal antibody-based pretreatment against botulinum neurotoxin. Continue studies utilizing human monoclonal antibodies against ricin toxin in assay development and post-exposure prophylaxis models.	6.389	12.126	17.971
Title: 4) Biosurveillance ***Description:*** Integrate existing disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced warning systems, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, impact and biological threat assessment. Contribute to the development of global, near real-	0.936	9.264	4.552

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
time, disease monitoring and surveillance systems that address secondary infection, fuse medical syndromic, environmental, and clinical data, and feed into disease modeling, medical resource estimation and decision support tools. ***FY 2015 Accomplishments:*** Completed the development of a scalable, replicable framework to serve as the basis for a biosurveillance cloud for Government data which delivered an analytic capability for the Biosurveillance (BSV) Ecosystem. Completed efforts using social media to infer individual and collective health behavior for digital threat surveillance, epidemic planning and response which delivered an analytic capability for the BSV Ecosystem. Continued the development of analytic capabilities to synthesize and interrogate multiple sources of data to provide high confidence in the prediction, early warning and forecasting (inclusive of mitigation strategies) of infectious disease outbreaks. Continued the development of the BSV Ecosystem to include analyst collaboration tools, advanced analytics, and analyst workbench. Continued the development and testing of a fieldable "smart trap" for long-term autonomous surveillance of arboviruses in mosquitoes. Initiated the development of various biosurveillance analytic capabilities including a Surveillance Window App (SWAP), a suite of five epidemiological tools for integration into the BSV Ecosystem, and a Biosurveillance Ecosystem evaluation support capability. Initiated a field forward diagnostic evaluation capability to assess technical feasibility and limitations of deploying point of need diagnostics in austere environments. ***FY 2016 Plans:*** Complete the development and testing of a fieldable "smart trap" for long-term autonomous surveillance of arboviruses. Continue the development of the BSV Ecosystem to include analyst collaboration tools, advanced analytics, and analyst workbench. Continue the development of various biosurveillance analytic capabilities including a SWAP, a suite of five epidemiological tools for integration into the BSV Ecosystem, and a BSV Ecosystem evaluation support capability. Continue the field forward diagnostic evaluation capability to assess technical feasibility and limitations of deploying point of need diagnostics in austere environments. ***FY 2017 Plans:*** Complete the development of the BSV Ecosystem platform to include analyst collaboration tools, advanced analytics, and analyst workbench. Complete the development of various biosurveillance analytic capabilities including a SWAP, and a suite of epidemiological forecasting and prediction tools. Continue the field forward diagnostic evaluation capability to assess technical feasibility and limitations of deploying point of need diagnostics in austere environments.			
Title: 5) Chemical Diagnostics ***Description:*** Focuses on state-of-the-art laboratory/fieldable methods that detect exposure to chemical warfare agents (CWA) (e.g., nerve agents and vesicants) in clinical samples. It also targets the identification of biomolecular targets that can be leveraged as analytical methodologies, as well as laboratory and animal studies characterizing time-course and longevity of a particular analyte/biomarker.	0.338	0.393	-

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
NOTE: Starting in FY17, program will be moved to TM3 - Diagnostics. ***FY 2015 Accomplishments:*** Continued the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs in clinical samples. Completed final stability tests and initiated discussion for the transitioning of the Forensic Liquid Analysis Kit (FLAK) to the Next Generation Diagnostic System. Continued development of new analytical methods against currently used methods. ***FY 2016 Plans:*** Continue the current set of analytical methods to more sensitive analytical platforms for the detection of CWAs in clinical samples.			
Title: 6) Diagnostic Device Platforms ***Description:*** Diagnostic device development to include systems able to harness next generation technologies to revolutionize clinical diagnostics in care facilities and in hospital laboratories. This investment will incorporate capabilities such as next generation sequencing and advanced biomolecular methods to harness both host and pathogen biomarkers in a threat agnostic approach that will serve all echelons of military medical care. Technology transitions to the Next Generation Diagnostic System. ***FY 2015 Accomplishments:*** Evaluated candidate host biomarker diagnostic targets in clinical test environments. Developed point-of-need diagnostic platforms with host biomarker diagnostic assays and test performance. Evaluated metrics of host-based diagnostics with pathogen detection approaches in analytical and/or clinical environments. Continued to develop candidate devices for potential transition to support the deployment of point of care diagnostic capabilities. Continued development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Verified clinical utility of host and pathogen biomarkers and integrated onto diagnostic platform prototypes that confer(s) the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies. Completed proof-of-concept for the development of a bioinformatics platform and transitioned Version 1.0 to the Global Biosurveillance Technology Initiative program. ***FY 2016 Plans:*** Continue to develop candidate devices for potential transition to support the development of point of care diagnostic capabilities. Continue development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Continue to verify clinical utility of host and pathogen biomarkers and integrate onto diagnostic platform prototypes that confer(s) the ability to identify and type novel infectious agents as a function of their relationship to previously characterized pathologies. Continue sequence based comprehensive identification and characterization platform development for field forward capability. ***FY 2017 Plans:*** Continue developing point-of-need diagnostic platforms with host biomarker diagnostic assays and testing performance. Continue evaluating metrics of host-based diagnostics with pathogen detection approaches in analytical and/or clinical environments.	17.409	20.435	16.354

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Complete the development of candidate devices for potential transition to support the development of point of care diagnostic capabilities, and initiate the verification and test validation for these candidate devices. Continue development of hardware solutions and assay formats to enable point of need diagnostic capabilities. Continue genomic-based and initiate proteomic-based comprehensive identification and characterization platform development for field forward capabilities. Continue optimization and enhancement of updated bioinformatics platform to support genomic and clinical informatics.			
Title: 7) Medical Countermeasures Initiative ***Description:*** The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing (MCM-ADM) as enablers of the advanced development and flexible manufacturing capability. The MCMI will be continued under TM3/Bacterial Therapeutics. ***FY 2015 Accomplishments:*** Continued development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continued to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. ***FY 2016 Plans:*** Continue development of human in vitro immune mimetic assays for FDA acceptance to enable rapid and accurate prediction of the human response to experimental vaccines and other MCMs. Continue to develop and make practical improvements to existing agile, flexible, manufacturing bioprocesses for the purpose of accelerating access to biodefense MCMs. Continue to develop agile, flexible manufacturing processes that are amenable to the DoD Advanced Development and Manufacturing capability (ADMc).	9.517	10.222	-
Title: 8) Neurologic Therapeutics ***Description:*** Focuses on therapeutic strategies to effectively minimize neurologic injuries resulting from exposure to chemical warfare agents (CWA). This effort involves the development of neuroprotectants, anticonvulsants, and improved therapies for brain enzyme reactivation. Supports eventual Food and Drug Administration (FDA) licensure of new compounds or to identify licensed products for use in the treatment of chemical warfare casualties. ***FY 2015 Accomplishments:*** Formal transition memorandum and technical information package (TIP) for scopolamine as an adjunct therapeutic was transferred to advanced development. Continued efforts supporting regulatory science to facilitate FDA licensure including in vitro and in vivo testing. ***FY 2016 Plans:***	1.464	1.220	0.405

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TM3 / *TECHBASE MED DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Maintain Absorption, Distribution, Metabolism and Excretion (ADME) Research Center of Excellence partnership to ensure capability for supporting regulatory science to facilitate FDA licensure. ***FY 2017 Plans:*** Maintain the ADMET CoE partnership and capability to ensure capability for development of and supporting regulatory science to facilitate FDA licensure of chemical therapeutics.			
Title: 9) Toxin Therapeutics ***Description:*** Identify, optimize and evaluate potential therapeutic candidates effective against biological toxin threat agents. ***FY 2015 Accomplishments:*** Continued evaluation of novel small molecule inhibitors for pharmacokinetic and toxicology profiles. Continued to test novel small molecule inhibitors in mouse model of BoNT A intoxication for efficacy. Initiated production, characterization, and evaluation of humanized antibody cocktail to prevent and/or treat BoNT intoxication. ***FY 2016 Plans:*** Continue characterization and evaluation of humanized pentavalent antibody cocktail to prevent and/or treat BoNT intoxication, advancing to preclinical studies. Complete testing of novel small molecule inhibitors in NHP model of BoNT A intoxication for efficacy. Finalize preclinical studies to advance antibody based therapeutic for staphylococcal enterotoxin B intoxication into phase I clinical trials.	0.606	9.312	-
Title: 10) Vaccine Platforms and Research Tools ***Description:*** Use novel technology and methods to support development of vaccine candidates. Conduct studies to determine potential immune interference between lead vaccine candidates, the effect of alternative vaccine delivery methods, and thermo-stabilization technologies on the efficacy of lead vaccine candidates. Identify correlates of protection in humans, and predict the success of lead vaccine candidates in humans. ***FY 2015 Accomplishments:*** Continued development of alternative production platforms applying them to current vaccine needs. Conducted side-by-side studies to identify optimal adjuvants against viral targets. ***FY 2016 Plans:*** Maintain studies that utilize clinical samples from Filovirus outbreaks in multiple international locations to refine definition of clinically relevant correlates of immunity. Evaluate novel adjuvants as platforms for utilization in biodefense vaccines. Develop and evaluate bridging strategies for interim fielding capability readiness. ***FY 2017 Plans:***	3.829	3.515	0.405

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TM3 / *TECHBASE MED DEFENSE (ATD)*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Down-select target antigens based on immunogenicity for Yersinia pestis (plague), Coxiella (Q-fever) and other relevant indications for production in plant-based vaccine platform. Continue platform vaccine assessment activities: Explore antigen candidates for type A Francisella tularensis (Tularemia) using the RNActive vaccine platform technology. (Moved from TM3 - MCMI.) Further evaluate and define the DNA-based and nanoparticle vaccine platforms and targeted vaccine delivery systems. (Transitioned from TM2 - Vaccine Platforms and Research Tools.)			
Title: 11) Viral Therapeutics ***Description:*** Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents. ***FY 2015 Accomplishments:*** Evaluated small molecules for filoviruses in non-human primate models. Continued a repurposing screening program to determine efficacy of FDA approved compounds against emerging infectious diseases and initiated nonclinical (GLP) studies for most promising compounds . Isolated human monoclonal antibodies that show in vitro activity against Sudan Ebolavirus. ***FY 2016 Plans:*** Evaluate immunotherapies for alphaviruses in small animal and non-human primate models. Continue a repurposing screening program to determine the efficacy of FDA approved compounds against emerging infectious diseases. Continue pre-clinical research required to submit IND applications to the FDA for additional products or additional product indications to refresh the viral therapeutics product pipeline. ***FY 2017 Plans:*** Continue to develop and evaluate broad spectrum therapies against various strains of alphaviruses. Evaluate human plasma from people exposed to the Sudan strain of Ebola to optimize a monoclonal or polyclonal cocktail for use as a prophylactic. Support diagnostic evaluation of clinical samples from West Africa to assess the efficacy of immune plasma from Ebola survivors as a potential treatment.	6.516	1.961	6.198
Title: 12) Viral Therapeutics - Ebola ***Description:*** Title X - Ebola Response ***FY 2015 Accomplishments:*** Accelerated Ebola Virus countermeasures development in response to the West Africa outbreak. Initiated pre-clinical research, including optimization, required to submit Investigational New Drug (IND) applications to the Food and Drug Administration (FDA) and conducted Phase I clinical safety studies for near-term candidate products targeting the Ebola virus. Continued development of a pan-Ebola antibody cocktail and evaluated cocktail efficacy in animal models. Optimized expression of ZMapp to enhance product output. Evaluated ZMapp in a non-human primate animal model to identify the optimal dosing regimen for therapeutic efficacy. Supported diagnostic evaluation of clinical samples from West Africa to assess the efficacy of immune plasma from	13.814	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Ebola survivors as a potential treatment. Reformulation of Ebola monoclonal antibodies therapies to provide a more stable formulation that is highly resistant to high temperature exposures, which will allow for room temperature storage and shipping without the need for a cold chain, thus greatly reducing the cost and logistics, particularly on the battlefield or in remote areas. Evaluated FDA-approved combination therapies for potential prophylactic activity against the Ebola virus.			
Title: 13) Viral Vaccines ***Description:*** Evaluates the best vaccine candidates for Alphaviruses and Filoviruses for effectiveness and duration of protective immune response against aerosol challenge in large animal models. Animal models will be developed to support FDA licensure of mature vaccine candidates. ***FY 2015 Accomplishments:*** Conducted Good Lab Practices (GLP) animal efficacy studies utilizing a candidate VEEV DNA vaccine delivered by in vivo electroporation, comparing intra-muscular or intra-dermal routes of administration. Continued to support model and assay development associated with pre-clinical studies of the Alphavirus replicon vaccine vector in coordination with the advanced developer. Conducted pilot studies to inform GLP natural history studies for Alphaviruses (WEVEEV) to initiate fulfillment of future FDA 'Animal Rule' requirements necessary for vaccine licensure. Continued the development of animals models for Alphaviruses (EEE and WEE), to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure. Conducted in-study portion of a Phase 1 trial to assess the safety, tolerability and immunogenicity of a Venezuelan equine encephalitis virus (VEEV) DNA vaccine in volunteers. Developed single-component vaccine for Zaire Ebolavirus utilizing the Ebola Zaire vaccine (rVSV, ZEBOV) platform and conducted non-clinical non-human primate protection and Phase 1 clinical dose-definition studies. ***FY 2016 Plans:*** Continue to support Alphavirus and Filovirus vaccine candidates by determining correlates of protective immunity. Continue natural history studies for Alphaviruses (W/E/VEEV) to fulfill future FDA 'Animal Rule' requirements necessary for vaccine licensure. Demonstrate proof-of-concept safety and immunogenicity with a monovalent Filovirus vaccine candidate. Develop and evaluate bridging strategies for interim fielding capability readiness. ***FY 2017 Plans:*** Continue studies toward the development of Alphavirus and Filovirus vaccine candidates. Develop multivalent Filovirus vaccine for Zaire and Sudan Ebolavirus and Marburg Marburgvirus, building on the Ebola Zaire vaccine (rVSV, ZEBOV) platform and experience. Continue FDA requested biodistribution and non-human primate efficacy studies for FDA Animal Rule licensure of the Ebola rVSV ZEBOV vaccine. Explore calibrated non-human primate animal models and challenges for Alphaviruses (W/E/VEEV). Continue non-clinical and clinical development of a Venezuelan equine encephalitis virus (VEEV) DNA vaccine. Explore accelerated pathways for VEEV DNA vaccine development [moved from TM2/Viral/Bacterial/Toxins Vaccines].	4.238	1.933	5.432
Title: 14) Viral Vaccines	8.480	-	-

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Description: Title X - Ebola Response ***FY 2015 Accomplishments:*** Determined appropriate human dosage for the rVSV uG Ebola vaccine and extended safety and efficacy data. Initiated biodistribution studies and transmission studies to support vaccine licensure.			
Title: 15) SBIR/STTR	-	1.811	-
FY 2016 Plans: SBIR/STTR - FY16 - Small Business Innovative Research.			
Accomplishments/Planned Programs Subtotals	102.610	93.725	83.838

C. Other Program Funding Summary ($ in Millions)

Line Item	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
• MB4: *MEDICAL BIOLOGICAL DEFENSE (ACD&P)*	114.230	79.516	65.648	-	65.648	61.660	41.306	29.440	50.001	Continuing	Continuing
• MC4: *MEDICAL CHEMICAL DEFENSE (ACD&P)*	0.000	0.000	5.681	-	5.681	0.000	0.000	0.000	0.000	0	5.681
• MB5: *MEDICAL BIOLOGICAL DEFENSE (EMD)*	169.400	107.883	106.223	-	106.223	170.667	190.756	188.537	181.318	Continuing	Continuing
• MC5: *MEDICAL CHEMICAL DEFENSE (EMD)*	25.966	42.911	39.504	-	39.504	44.656	25.358	11.155	4.855	Continuing	Continuing
• MB7: *MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)*	13.186	11.801	7.145	-	7.145	9.575	16.516	13.931	13.338	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program			Date: February 2016
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COST ($ in Millions)	Prior Years	FY 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
TT3: *TECHBASE TECHNOLOGY TRANSITION*	-	5.635	7.359	7.821	-	7.821	10.867	10.378	11.150	11.152	Continuing	Continuing

A. Mission Description and Budget Item Justification

Project TT3 validates high-risk/high-payoff technologies, concepts-of-operations, and a Joint Combat Development concept development and experimentation process that could significantly improve Warfighter capabilities in preparation for transition of mature technologies to advanced development programs requiring chemical and biological (CB) defense technologies. These programs offer an opportunity to identify and efficiently mature emerging technologies including limited objective experiments, laboratory experiments, risk reduction efforts, engineering and integration. These demonstrations and programs 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. This project addresses four family of products areas: Biological Resiliency, to include Biosurveillance; Integrated Early Warning, to include Remote Detection; Chemical and Biological Warfare Agent Destruction and Disablement; and Hazard Mitigation. Biological resiliency efforts are targeted to reduce biological threats. Integrated Early Warning is conducted through a coordinated program approach focused on layering Chemical and Biological Detection technologies and integrating CB threat indicators with rapid response actions. WMD Disablement and Destruction addresses detection, identification, verification and baseline assessments in support of expeditionary forces deployed in non-permissive environments. Hazard Mitigation addresses Chemical, Biological, and Radiological (CBR) remediation and decontamination processes.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
Title: 1) Experiment & Technology Demonstrations	5.635	7.206	7.821
Description: Project TT3 validates high-risk/high-payoff technologies and concepts-of-operations through the use of the Advanced Technology Demonstration (ATD) and Rapid Military Utility Assessment (RMUA) processes. The RMUA is a development and experimentation process that could significantly improve Warfighter capabilities through the efficient transition of mature technologies to Advanced Component Development and Prototype programs. This project addresses four family of products areas: Biological Resiliency, to include Biosurveillance; Integrated Early Warning, to include Remote Detection; Chemical and Biological Warfare Agent Destruction and Disablement; and Hazard Mitigation.			
FY 2015 Accomplishments: Completed and transitioned Coalition Warfare Program S&T efforts with Poland to OSD-ATL, which aimed at improving biological agent standoff detection. As part of the Transatlantic Collaborative Biological Resiliency Demonstration (TaCBRD), conducted extended user evaluation of capabilities for persistent and contagious bio agent scenarios in the US European Command Area of Responsibility (EUCOM AOR). These capabilities recently transitioned to the JPM-Guardian, JPM-Information Systems, and JPM-NBC Contamination Avoidance for potential inclusion into multiple PORs and Poland Ministry of Defense. Initiated			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TT3 / *TECHBASE TECHNOLOGY TRANSITION*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2015	FY 2016	FY 2017
biosurveillance and rapid response ATD, named Homeland Integrated Biosurveillance Response and Information Demonstration (HIBRID), in the U.S. Pacific Command (PACOM) AOR through FY18. Conducted a rapid military utility assessment and field experiment process to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. Completed demonstration of decontamination technologies for airframe interiors and exteriors against bio agents as part of a JCTD initiative with US TRANSCOM, allowing aircraft to return to service and achieving considerable cost savings over the alternative of removing those assets from service. Completed and transitioned the Thermal Imaging Dual-use for Aerosol Monitoring Alarms and Security (TIDAMAS) ATD to Joint Project Manager-Guardian for detection of biological threat aerosol attacks, which allows for enhanced integrated base defense posture and protection of critical DoD infrastructure. JPM-Guardian will continue to conduct advanced development of TIDAMAS in support of the DoD Physical Security Enterprise and Analysis Group (PSEAG). Initiated risk reduction activities in preparation for the WMD expeditionary disablement ATD and a proposed mass casualty decontamination and medical support ATD for a planned FY16 start. ***FY 2016 Plans:*** Develop and demonstrate prototypes and technologies for the expeditionary and disablement ATD. For the DoD/DHS collaborative biosurveillance ATD, begin technology and CONOPS/TTP development and system integration of information systems for the whole of Government. Continue to conduct rapid military utility assessments and field experiments process to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer and with outcomes to support warfighter requirements and capability development. Initiate risk reduction activities for a comprehensive early warning ATD scheduled to commence in FY17. Focus of activities will be to develop an architecture for the development of sensor and mobile platforms along with methods of information sharing to enable early warning in forward deployed locations. ***FY 2017 Plans:*** Continue to develop and demonstrate prototypes and technologies for the WMD expeditionary disablement ATD which will address WMD rapid disablement and destruction program area in support of key operational planning scenarios. Initiate S&T integration activities for CB sensor technologies onto mobile platforms as part of the comprehensive early warning ATD. Conduct risk reduction activities for the development and integration of wearable sensors as part of the comprehensive early warning ATD. Continue to conduct rapid military utility assessments and field experiments to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. Continue risk reduction activities through baseline assessments in preparation for a mass casualty decontamination and medical support ATD.			
Title: 2) SBIR/STTR ***FY 2016 Plans:*** SBIR/STTR - FY16 - Small Business Innovative Research.	-	0.153	-
Accomplishments/Planned Programs Subtotals	5.635	7.359	7.821

Exhibit R-2A, RDT&E Project Justification: PB 2017 Chemical and Biological Defense Program		Date: February 2016
Appropriation/Budget Activity 0400 / 3	**R-1 Program Element (Number/Name)** PE 0603384BP / *CHEMICAL/BIOLOGICAL DEFENSE (ATD)*	**Project (Number/Name)** TT3 / *TECHBASE TECHNOLOGY TRANSITION*

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A