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Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Chemical and Biological Defense Program **Date:** March 2019

Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide I BA 3: Advanced Technology Development (ATD)</i>					R-1 Program Element (Number/Name) PE 0603384BP I <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	-	141.242	142.826	172.486	-	172.486	191.380	192.619	186.918	186.307	Continuing	Continuing
CB3: <i>CHEMICAL BIOLOGICAL DEFENSE (ATD)</i>	-	16.878	21.698	16.798	-	16.798	22.039	22.538	22.833	21.682	Continuing	Continuing
NT3: <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>	-	20.781	22.749	24.180	-	24.180	30.295	31.085	31.076	31.071	Continuing	Continuing
TM3: <i>TECHBASE MED DEFENSE (ATD)</i>	-	92.231	88.188	120.526	-	120.526	128.035	127.992	122.006	122.553	Continuing	Continuing
TT3: <i>TECHBASE TECHNOLOGY TRANSITION</i>	-	11.352	10.191	10.982	-	10.982	11.011	11.004	11.003	11.001	Continuing	Continuing

A. Mission Description and Budget Item Justification

The projects in this program element (PE) demonstrate technologies supporting transition to advanced component development for 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 early warning 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.

Individual projects include:

- Chemical Biological Defense (CB3): demonstrations of CB physical science defense technologies, including biological detection, chemical detection, digital battlespace management, and protection, and decontamination. The Project continues to pursue solutions against traditional agents.

- NTA Defense (NT3): dedicated research (both medical and non-medical) is consolidated in NT3. This effort includes NTA chemical diagnostics, medical pretreatments, therapeutics, detection, and protection and hazard mitigation.

- Medical Defense (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.

- Technology Transition (TT3): pursues federal R&D or commercially available products 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 CBDP S&T Advanced Technology Development stakeholders: United States Army Edgewood Chemical Biological Center (ECBC), 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.

This 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 and PE 0604384BP activities.

B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	145.359	142.826	150.168	-	150.168
Current President's Budget	141.242	142.826	172.486	-	172.486
Total Adjustments	-4.117	0.000	22.318	-	22.318
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	-			
• Congressional Directed Transfers	0.000	-			
• Reprogrammings	-0.974	-			
• SBIR/STTR Transfer	-3.143	-			
• Other Adjustments	0.000	-	22.318	-	22.318

Change Summary Explanation

Funding: FY18 (-\$0.974M): Reprogramming adjustments to balance overall portfolio efforts.

FY18 (-\$3.143M): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY20 (+\$31.400M): Increase for Medical Countermeasures Initiative and CBDP Support to Bio-Incident Response.

FY20 (-\$9.082M): Funds transferred to BA2 - Threat Agent Science portfolio to expand threat characterization and assessments to minimize surprise from emerging and advanced CBRN threats

Schedule: N/A

Technical: N/A

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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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
CB3: CHEMICAL BIOLOGICAL DEFENSE (ATD)	-	16.878	21.698	16.798	-	16.798	22.039	22.538	22.833	21.682	Continuing	Continuing

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. 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.

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

	FY 2018	FY 2019	FY 2020
Title: 1) Expeditionary Collective Protection	0.723	0.106	0.639
Description: Develop new technologies for soldiers to determine the remaining chemical vapor service life of their chemical warfare agent (CWA) filters.			
FY 2019 Plans: - Continue from FY18 CB3 (Chemical Biological Defense)/Expeditionary Collective Protection integration and surveillance of Guard Bed filters and residual life indicator (RLI). - Continue to pull satellite cartridges and the primary ColPro filter (M98) filters for surveillance testing and assessment. This effort is ongoing to FY21.			
FY 2020 Plans: - Continue testing of RLI and Guard Bed systems and evaluating data obtained at fixed site locations and provide final report. - Continue scale up materials successfully tested and integrate into filters for testing against threat agents of interest.			
FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.			
Title: 2) Material Contamination Mitigation	1.626	1.912	1.952
Description: Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort.			
FY 2019 Plans:			

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Transition sorbent decontaminant formulation effort to advanced development for tactical decontamination. - Complete vapor and complex surface efficacy performance evaluations and technical demonstration to support relevant data development to transition at TRL6. - Continue coatings optimization utilizing new chemical agent resistance method to reduce chemical absorption. - Continue Wide Area Decontamination of Bacillus anthracis projects, focusing on varied subscale testing environments. - Continue to optimize the decontamination parameters for the hot air biological decontamination effort, including the introduction of germinates to address sensitive equipment, platform interior, and aircraft decontamination needs and reduce the time and logistical burden associated with the process. - Continue chemical hot air decontamination effort including the insertion of aerosolized decontaminants to reduce the time and logistical requirements associated with addressing sensitive equipment, platform interior, and aircraft chemical warfare agent decontaminant needs in a relevant environment. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Complete development of Wide Area Decontamination of Anthrax agricultural spray technology focusing on testing in outdoor environments and related data analysis from demonstrations. - Continue evaluation of disclosure spray in low light and other relevant environments. - Continue evaluation and testing of hot air decontamination of equipment and personal effects. - Complete optimization of chemical hot air decontamination process and transition to advance development. - Continue scale up materials successfully tested and integrate into filters for testing against threat agents of interest. - Initiate demonstration of temporary coatings to improve vehicle decontaminability. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>					
<p>Title: 3) Percutaneous Protection</p> <p>Description: Develop advanced ensemble prototypes with state-of-the art materials that address the full spectrum of threats and provide a range of solutions optimized for protection, thermal comfort, and mission performance.</p> <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Continue investigation of materials and integration of successfully tested materials into fibers, fabrics, yarns and elastomeric materials. - Continue data evaluation from Chemical and Biological Operational Assessment reporting and technical assessments to inform system design and final technical and user assessments against chemical and biological threats. - Complete development of Level A/B All Hazards ensembles and transition to advance development. 			0.690	-	0.285

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
- Continue scale up materials successfully tested and integrate into filters for testing against threat agents of interest.					
FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.					
Title: 4) Respiratory and Ocular Protection Description: Develop novel filtration media that are lighter weight and lower burden while capable of protecting against a broader range of challenges that includes toxic industrial chemicals (TICs). FY 2019 Plans: - Continue to acquire and assemble Closed Circuit Self Contained Breathing Apparatus (CC-SCBA) subsystems into a hybrid technology prototype system. Build and test Full-Spectrum Respiratory Protection System (FSRPS) prototypes that include all sensors and control technology solutions. - Continue to scale up nano-structured porous materials for air purification. - Continue to conduct performance evaluation and demonstration of FSRPS prototypes. - Continue to assess novel filtration materials against new emerging threats. FY 2020 Plans: - Continue scale up materials successfully tested and integrate into filters for testing against threat agents of interest. - Complete development and transition of FSRPS that provide CB respiratory protection technologies in support of tactical all hazard program of record. FY 2019 to FY 2020 Increase/Decrease Statement: Decrease due to change in program/project schedule.			1.136	1.975	0.962
Title: 5) 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. This program is transferring to CB3 M&S (Chemical Biological Defense) Threat Surveillance in FY19.			2.325	-	-
Title: 6) Detection			2.693	6.122	6.156

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<p>Description: Advance and mature technologies and capabilities to detect and identify chemical and biological threats to the point of transitioning to customers for advanced development. This activity can include development of point, remote, or standoff sensors as appropriate, to address both chemical and biological threats. These efforts develop transitionable detection capabilities for early warning of contamination exposure to the warfighter.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Complete the development of sample preparation techniques to enhance environmental detection platforms. - Continue the development of proteomic detection capabilities, to include expansion into the methodologies to detect novel threats. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Continue the development of proteomic detection capabilities, to include expansion into the methodologies to detect novel threats. - Continue development of CB sensors for mobile applications to enhance early warning and situational awareness of CB threats. - Initiate development of CB sensors for distributed reconnaissance purposes. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>					
<p>Title: 7) Hazard Prediction</p> <p>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 toxic industrial materials.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Continue performance optimization and high fidelity enhancements for transport and dispersion models, particularly for urban environments. - Continue configuration management of science and technology prototype for transition of upgraded capabilities to Joint Effects Model (JEM). - Continue upgrading science and technology prototype to Common CBRN Modeling Interface (CCMI) architecture. - Complete validation and verification (V&V) studies for high fidelity source term algorithms. <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p>			-	5.782	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
Decrease due to change in program/project technical parameters. Program will transfer to CB3 Decision Analysis and Management in FY20.					
<p>Title: 8) Hazard Prediction</p> <p>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 toxic industrial materials.</p> <p>CB3 M&S DST transferred to CB3 M&S in FY19.</p>			3.404	-	-
<p>Title: 9) Data Analysis</p> <p>Description: Develop CBRN 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.</p>			0.029	-	-
<p>Title: 10) Data Analysis</p> <p>Description: Develop CBRN 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.</p> <p>Program will transfer to CB3 Decision Analysis and Management in FY20.</p> <p>FY 2019 Plans:</p> <p>- Complete the digitization effort at the United States Army Heritage and Education Center and make the digitized documents accessible through CB-1s online portal.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p> <p>Decrease due to change in program/project technical parameters.</p>			-	0.103	-
<p>Title: 11) Operational Effects</p> <p>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 Chemical Biological Radiological and Nuclear</p>			-	2.027	-

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
(CBRN) incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management. Program will transfer to CB3 Decision Analysis and Management in FY20. FY 2019 Plans: - Continue Decontamination and Individual Protection SPM integration and advanced development. FY 2019 to FY 2020 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.					
Title: 12) 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 Chemical Biological Radiological and Nuclear (CBRN) incidents on decision-making. Focus areas include consequence management, population modeling, and knowledge management.			4.252	-	-
Title: 13) Decision Analysis and Management Description: Enable the prediction of chemical and biological hazards, exposures, casualties, and infections along with providing timely and accurate warnings and recommended courses of action. Develop methods to utilize non-traditional detection methods to provide indications of Chemical and Biological exposure risk. FY 2020 Plans: - Mature comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, and burden estimates from contagious infectious disease outbreaks. Incorporate uncertainty estimates into disease forecasting and prediction models. - Mature data visualization displays of disease model outputs. Incorporate newly characterized threat agent properties into hazard prediction models. - Continue performance optimization and high fidelity enhancements for transport and dispersion models, particularly for urban environments. - Continue development of coupled indoor and outdoor dispersion models for enhanced hazard prediction in urban environments to include advanced methods for interior to exterior transport, uncertainty estimation, and upgrades to user interface. - Continue configuration management of science and technology prototype for transition of upgraded capabilities to Joint Effects Model (JEM).			-	-	5.783

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Complete upgrades to science and technology prototype modules to meet Common CBRN Modeling Interface (CCMI) architecture requirements. - Develop algorithms to leverage non-invasive host based devices to provide earlier warning of chemical and biological threats and/or exposure. - Develop automated decision aids and reference guides to assist tactical users in properly responding to chemical and biological threats. Develop a tool to support the DoD in responding to a CBRN incident, a toxic industrial chemical (TIC) release, or a contagious epidemic by providing a means of calculating the medical resource requirements necessary to successfully manage the civilian and military consequences. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters. This program will subsume CB3 Hazard Prediction, Operational Effects and Planning, Data Analysis in FY20.</p>					
<p>Title: 14) Threat Surveillance</p> <p>Description: Integrate disparate military and civilian datasets, investigate methodologies to appropriately integrate open source data into advanced chemical and biological threat warning systems, tactical decision aids, and leverage and enhance advanced epidemiological models and algorithms for disease prediction, forecasting, impact and biological threat assessment.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Identify sources for pathogen data and develop tools to mine data sources (PubMed, Google Books, online journals) to create a comprehensive human, animal, and plant pathogen database. Link pathogen database to disease ontologies and develop the capability for automatic pathogen updates from newly published data. - Enhance the Biosurveillance Ecosystem (BSVE) framework to support the rapid integration of multiple data sources, tools, algorithms, and services that support chemical and biological defense. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. This program subsumes CB3 Biosurveillance and TM3 Biosurveillance efforts in FY19. In FY20, this program will transfer to CB3 Warning and Reporting.</p>			-	3.671	-
<p>Title: 15) Warning and Reporting</p> <p>Description: Develop a framework for integrating and correlating timely, relevant information sources. Investigate new approaches and methodologies such as machine learning, artificial intelligence, and advanced data analysis to accelerate analytical processes and provide early warning of chemical and biological threats.</p> <p>FY 2020 Plans:</p>			-	-	1.021

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B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020
<div>- Develop and implement data standards for the transmission and storage of information sources relevant to the earlier warning of chemical and biological threat agents. Broaden the utility of a previously developed framework to include both tactical and non-specialized users.</div> <div>- Continue research and analysis efforts to provide objective, quantitative analysis in support of science and technology initiatives, material developments, operational guidance, and requirements settings.</div> <div>- Initiate transition of the Individual Protection System Performance Model to Service users.</div> <div>- Continue the advanced development of the Decontamination System Performance Model.</div> <div>- Continue to host CB-1 and start review of user feedback for periodic updates to CB-1 material.</div> <div>- Initiate digitization of historic data and information pertaining to Chemical and Biological warfare at other sites with relevant archival holdings.</div> <div>- Initiate integration of Graphics Processing Units methodologies into hazard prediction software and initiate user testing.</div> <div>FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters. CB3 Threat Surveillance will transfer to this program in FY20.</div>											
Accomplishments/Planned Programs Subtotals									16.878	21.698	16.798
C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
• CA4: CONTAMINATION AVOIDANCE (ACD&P)	30.844	31.527	19.074	-	19.074	8.864	8.215	15.106	13.706	Continuing	Continuing
• DE4: DECONTAMINATION SYSTEMS (ACD&P)	9.888	6.117	8.735	-	8.735	10.258	9.511	6.044	5.905	Continuing	Continuing
• IS4: INFORMATION SYSTEMS (ACD&P)	5.336	0.854	0.528	-	0.528	0.174	0.070	0.067	0.067	Continuing	Continuing
• TE4: TEST & EVALUATION (ACD&P)	9.097	6.563	5.162	-	5.162	5.156	3.541	3.541	3.541	Continuing	Continuing
Remarks											
D. Acquisition Strategy N/A											
E. Performance Metrics N/A											

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COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
NT3: TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)	-	20.781	22.749	24.180	-	24.180	30.295	31.085	31.076	31.071	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.

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.

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.

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

	FY 2018	FY 2019	FY 2020
Title: 1) Material Contamination Mitigation	1.015	0.128	0.520
Description: Develop highly effective non-traditional or novel decontamination technologies that integrate with current procedures and support non-material improvements of the overall decontamination effort.			
FY 2019 Plans:			
- Continue responsive coatings optimization against emerging threats under relevant environmental conditions and identifying potential battlefield interferants.			
- Continue development and optimization of the full range of NTAs, including other emerging threats into the material contamination mitigation portfolio under relevant environmental conditions.			
- Continue to integrate NTA testing into hot air decontamination effort to address sensitive equipment, platform interior, and aircraft NTA decontaminant needs in a relevant environment and identifying potential battlefield interferants.			

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<p>- Continue optimization efforts to develop/enhance NTA mapping (disclosure/assurance) technologies in simulated relevant environments.</p> <p>FY 2020 Plans:</p> <p>- Complete optimization of chemical hot air decontamination process and transition to advance development. Perform field trials under relevant conditions e.g. complex surfaces, and dirty/fouled surfaces against advanced threats.</p> <p>- Continue integration of successfully tested materials capable of sorption and reaction of NTAs for next generation filter applications.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p> <p>Increase due to fact of life change in the program/project.</p>					
<p>Title: 2) Personnel Contamination Mitigation</p> <p>Description: Develop new technologies to mitigate 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.</p> <p>FY 2019 Plans:</p> <p>- Continue personnel decontamination efforts to enhance current processes including efficacy data against representative NTAs and emerging threats in relevant environments and identifying battlefield interferants.</p> <p>FY 2020 Plans:</p> <p>- Assess decontamination effectiveness of different methods of applying decontamination to hair and skin to discern the most efficient way of decontaminating personnel against NTAs and advanced threats.</p> <p>- Continue integration of successfully tested materials capable of sorption and reaction of NTAs for next generation filter applications.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p> <p>Increase due to change in program/project technical parameters.</p>			0.757	0.354	0.408
<p>Title: 3) Respiratory and Ocular Protection</p> <p>Description: Development and analysis of design alternatives for chemical and biological air-purifying respirators that provide enhanced protection with lower physiological burden and improved interface with mission equipment.</p> <p>FY 2019 Plans:</p> <p>- Continue to acquire and assemble closed circuit self-contained breathing apparatus (CC-SCBA) subsystems into a hybrid technology prototype system. Build and test FSRPS prototypes that include all sensors and control technology solutions.</p>			0.307	1.811	0.688

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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<div>- Continue to scale up nano-structured porous materials for air purification.</div> <div>- Continue to conduct performance evaluation and demonstration of full spectrum respiratory protection system (FSRPS) prototypes.</div> <div>- Continue to assess novel filtration materials against new emerging threats.</div> <div>FY 2020 Plans:</div> <div>- Continue integration of successfully tested materials capable of sorption and reaction of NTAs for next generation filter applications.</div> <div>- Continue refining technologies that enhance face-piece seals performance, lens fogging resistance, and comfort and demonstrate refined full spectrum respiratory protection system (FSRPS) prototype.</div> <div>FY 2019 to FY 2020 Increase/Decrease Statement:</div> <div>Decrease due to change in program/project schedule.</div>					
<div>Title: 4) Therapeutics - Medical</div> <div>Description: Efforts in this area advance the understanding of mechanisms of action for NTAs and emerging chemical threats by probable routes of field exposure and seek to refine effectiveness of therapeutics to advance therapeutic development. Physiological parameters and pathological assessments will be used to establish the general mode and mechanisms of toxicity required for therapeutic development.</div> <div>FY 2019 Plans:</div> <div>- Continue investigating technologies to deliver therapeutics to the brain.</div> <div>- Continue evaluating novel therapeutics using high-throughput in vitro screens.</div> <div>- Continue optimization on novel therapeutic compounds.</div> <div>- Continue validating animal models for use in NTA exposure studies.</div> <div>FY 2020 Plans:</div> <div>- Continue investigating technologies for delivering therapeutics to the brain.</div> <div>- Continue optimizing and evaluating novel therapeutic in animal models and initiate preclinical studies in support of investigative new drug (IND) submission.</div> <div>- Initiate drug repurposing effort to identify therapeutics for selected NTAs.</div> <div>FY 2019 to FY 2020 Increase/Decrease Statement:</div> <div>Increase due to change in program/project technical parameters.</div>			2.768	3.118	4.436
Title: 5) Detection			11.110	11.283	11.434

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
Appropriation/Budget Activity 0400 / 3		R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		Project (Number/Name) NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
Description: Focuses on technologies to provide NTA detection capabilities. FY 2019 Plans: - Complete prototype of chemical sensors for persistent sensing and chemical reconnaissance applications. - Complete the development of a man worn environmental sensor for detecting exposure to chemical hazards. Transitioning to Wearable Chemical Agent Detector (WCAD). FY 2020 Plans: - Initiate the development of detection technologies to provide a handheld chemical survey tool to detect and locate deposited liquid and solid threats on surfaces. - Initiate the development of sensor technologies against non-traditional threats of concern. FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.					
Title: 6) 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 2019 Plans: - Complete system performance model integration and development for program-wide exploitation for decontamination. FY 2020 Plans: - Perform research studies to provide objective, quantitative analyses in support of science and technology initiatives, material developments, and operational guidance for the Chemical and Biological Defense Program.			0.206	0.236	0.236
Title: 7) Percutaneous Protection Description: Develop advanced ensemble prototypes with state-of-the art materials that address the full spectrum of threats and provide a range of solutions optimized for protection, thermal comfort, and mission performance. FY 2020 Plans: - Continue investigation of new/novel sorptive materials for percutaneous protection and integrate into fabrics, yarns, fibers for testing against chemical and biological agents.			0.157	-	0.588

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
Appropriation/Budget Activity 0400 / 3		R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>		Project (Number/Name) NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
- Continue final technical and user assessments against nontraditional agents (NTAs) and emerging threats on the tactical all hazards suits.					
FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.					
Title: 8) Test & Evaluation Description: Develop test and evaluation technologies and processes in support of NTA activities. FY 2019 Plans: - Complete the rapid prototyping and evaluation of chemical detection platforms, specifically addressing vapor passive sensing, identification of liquid chemical threats, and the detection of solids. FY 2020 Plans: - Complete the rapid prototyping and evaluation of chemical detection platforms addressing man-worn vapor detection technologies. - Continue rapid prototyping and evaluation of chemical detection platforms addressing standoff chemical detection capabilities. - Initiate rapid prototyping and evaluation of chemical detection platforms addressing distributed CB reconnaissance capabilities. FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.			0.841	0.776	0.785
Title: 9) Pretreatments and Prophylactics - Medical Description: Develop pretreatments and prophylactics that provide protection against NTAs and emerging chemical threats. Prophylactic scavengers should rapidly detoxify a broad spectrum of compounds of interest (COIs). FY 2019 Plans: - Initiate studies to support clinical development of prophylaxis for selected NTAs if warranted based upon data from FY18 proof-of-concept studies. - Continue efforts to develop two organophosphorus nerve agents (OPNA) scavenger enzymes to meet requirements of a prophylactic medical countermeasure. FY 2020 Plans: - Continue efforts to develop OPNA catalytic scavenger enzymes in support of investigational new drug (IND) submission to the FDA.			3.620	5.043	5.085

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program										Date: March 2019		
Appropriation/Budget Activity 0400 / 3				R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>				Project (Number/Name) NT3 / <i>TECHBASE NON-TRADITIONAL AGENTS DEFENSE (ATD)</i>				
B. Accomplishments/Planned Programs (\$ in Millions)										FY 2018	FY 2019	FY 2020
- Initiate prophylactic studies of Medical Countermeasures (MCMs) against additional selected NTAs and continue efforts as needed.												
FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.												
Accomplishments/Planned Programs Subtotals										20.781	22.749	24.180
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
• CA4: <i>CONTAMINATION AVOIDANCE (ACD&P)</i>	30.844	31.527	19.074	-	19.074	8.864	8.215	15.106	13.706	Continuing	Continuing	
• DE4: <i>DECONTAMINATION SYSTEMS (ACD&P)</i>	9.888	6.117	8.735	-	8.735	10.258	9.511	6.044	5.905	Continuing	Continuing	
• IP4: <i>INDIVIDUAL PROTECTION (ACD&P)</i>	4.421	3.228	1.997	-	1.997	1.997	2.994	0.000	0.000	0.000	14.637	
• MC4: <i>MEDICAL CHEMICAL DEFENSE (ACD&P)</i>	4.666	2.388	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	7.054	
• TE4: <i>TEST & EVALUATION (ACD&P)</i>	9.097	6.563	5.162	-	5.162	5.156	3.541	3.541	3.541	Continuing	Continuing	
Remarks												
D. Acquisition Strategy N/A												
E. Performance Metrics N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program										Date: March 2019		
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 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
TM3: TECHBASE MED DEFENSE (ATD)	-	92.231	88.188	120.526	-	120.526	128.035	127.992	122.006	122.553	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.

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.
- 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.

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

	FY 2018	FY 2019	FY 2020
Title: 1) Assays and Reagents 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. This program is transferring in FY19 to TM3 (Techbase Med Defense) Medical Diagnostics.	27.423	-	-
Title: 2) Bacterial Therapeutics Description: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents. FY 2019 Plans: <ul style="list-style-type: none"> - Continue multiple efforts to advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward investigative new drug (IND) and phase I clinical studies. Complete optimization of dosing regimen and formulation of a novel orally-delivered therapeutic in models of <i>B. pseudomallei</i> infection. - Continue strategy to engage industry in the development of therapeutics for Biowarfare agent indications through the evaluation of late development and/or FDA approved compounds for efficacy in pivotal Good Laboratory Practices Non-Human Primate 	15.733	17.580	12.058

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
(GLP NHP) models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a supplemental New Drug Application (sNDA) under the Animal Rule. FY 2020 Plans: - Continue multiple efforts to advance candidate therapeutics, with a focus on non-traditional candidates, through preclinical evaluation toward IND and phase I clinical studies. File IND for a novel orally-delivered therapeutic for treatment of B. pseudomallei infection. - Continue strategy to engage industry in the development of therapeutics for Biowarfare agent indications through the evaluation of late development and/or FDA approved compounds for efficacy in pivotal GLP NHP models against aerosolized challenge of Yersinia pestis, Bacillus anthracis, or Francisella tularensis in support of submission of a sNDA under the Animal Rule. FY 2019 to FY 2020 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. FY20 decrease due to significant investments in pre-clinical development of candidates concluded in FY19, replacements have been selected, awards are pending and subject to availability of funds.				
Title: 3) Bacterial/Toxin Vaccines Description: Evaluate the best single agent bacterial and toxin vaccines and pretreatments for effectiveness against aerosol challenge in large animal models. FY 2019 Plans: - Complete validation of T cell and B cell epitopes and antigens for Q Fever vaccine design and testing. - Complete down-selection of live attenuated Tularemia vaccine candidates for advancement into manufacturing and clinical development. - Continue manufacturing development and IND enabling studies of Outer Membrane Vesicle (OMV) and other lead Burkholderia candidates based on results in animal models. - Continue development of human monoclonal antibodies to ricin toxin selected from vaccinated volunteers. - Continue evaluation of efficacy and conjugate production and formulation of capsule conjugate anthrax vaccine in combination with Protective-antigen (PA)-based vaccine. Define correlate of immunity of next generation CPS conjugate anthrax vaccine. - Continue evaluation and manufacturing development of Burkholderia OMV vaccine. - Continue animal-rule efficacy studies of multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin in relevant animal models. - Complete botulinum toxin mAb manufacturing and formulation development and release assay qualification and validation including reference standards. - Complete botulinum toxin mAb manufacture and prepare IND.		17.694	17.871	14.518

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<p>- Initiate formulation development and efficacy studies of pentavalent mAb product against botulinum intoxication targeting serotypes ABCDE.</p> <p>FY 2020 Plans:</p> <p>- Complete nonclinical efficacy and toxicology of Burkholderia OMV vaccine and subunit vaccine for advancement to clinical phase I.</p> <p>- Complete IND enabling efforts and filings in support of human clinical trials for animal-rule licensure of the multivalent monoclonal antibody cocktail for protection against A and B serotypes of botulinum neurotoxin.</p> <p>- Continue IND enabling development of live-attenuated tularemia vaccine.</p> <p>- Continue evaluation of efficacy and capsule conjugate manufacturing process development and formulation for next generation anthrax vaccine in combination with Protective-antigen (PA)-based vaccine.</p> <p>- Continue to refine correlates of immunity of next generation CPS conjugate anthrax vaccine.</p> <p>- Continue Burkholderia and Q fever seroprevalence studies in support of potential clinical trials, reagent generation and biomarker discovery.</p> <p>- Initiate Phase 1 clinical trial for multivalent monoclonal antibody cocktail.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p> <p>Decrease due to change in program/project technical parameters. Program efforts are reduced due to completion of ADAMANT BoNT mAb cGMP manufacturing, investigational new drug (IND) studies, and completion of ADAMANT BoNT phase I trial planning as well as termination of rPA based anthrax vaccine development.</p>					
<p>Title: 4) Biosurveillance (BSV)</p> <p>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.</p> <p>This program is transferring in FY19 to CB3 (Chemical Biological Defense) Threat Surveillance.</p>			6.166	-	-
<p>Title: 5) Diagnostic Device Platforms</p> <p>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.</p>			10.021	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
This program is transferring in FY19 to TM3 (Techbase Med Defense) Medical Diagnostics.					
Title: 6) Medical Countermeasures Initiative Description: The MCMI will integrate the regulatory science and manufacturing technologies and processes developed into the Advanced Development and Manufacturing Facility (MCM-ADM) to support establishment of platform capabilities as enablers of the advanced development of CBDP medical countermeasure products. These initiatives will lead to the development of multi-use platforms that have the potential to accelerate medical product development and/or regulatory approval as well as reduce overall development costs. FY 2020 Plans: <ul style="list-style-type: none"> - Continue to invest in monoclonal antibodies technologies to counter threat agents both prophylactically and therapeutically; - Invest in novel expression systems, including outer membrane vesicle based bacterial expression platforms for bacterial vaccine candidates; - Invest in novel platform technologies to support medical countermeasure candidate development, including the conjugate polysaccharide based vaccine platform and the DNA vaccine platform; - Invest in technologies that support regulatory science; - Invest in animal model development to support test and evaluation of MCMs and capability to respond to emerging threats; - Support manufacturing advancements for biologics. FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.			-	-	20.900
Title: 7) 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 2019 Plans: <ul style="list-style-type: none"> - Continue development of methods for evaluation of non-lethal symptomology and biomarkers of alphavirus infection in nonhuman primates (NHPs). - Continue development of outer membrane vesicles (OMV) and nanoparticle vaccine platforms targeting Burkholderia, Francisella and Yersinia. - Continue development of native conformation membrane protein expression and presentation system. 			3.102	2.976	6.358

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Continue advancement of manufacturing and formulation for Venezuelan equine encephalitis virus (VEEV) and Eastern equine encephalitis virus (EEEV) for entry to clinical studies. - Continue IND enabling studies with new formulation and delivery method for VEEV, EEV and WEEV vaccine. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Down select and qualify biomarkers of nonlethal alphavirus disease in NHPs. - Continue assay development to qualification/validation for advanced studies. - Continue manufacturing development of OMV and nanoparticle vaccine platforms targeting Burkholderia, Francisella and Yersinia. - Initiate assay qualification for OMV vaccine in advance of clinical studies. - Continue development of native conformation membrane protein expression and presentation system. - Initiate manufacturing and development of next generation plague monoclonal antibody cocktail. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>					
<p>Title: 8) Viral Therapeutics</p> <p>Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Continue small molecule and monoclonal antibody selection and evaluation in NHP models for pan-ebola/pan-filovirus and alphaviral therapeutic applications. - Continue monoclonal antibody development for broad spectrum capabilities. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Continue small molecule and monoclonal antibody selection and evaluation in NHP models for pan-ebola/pan-filovirus and alphaviral therapeutic applications. - Continue joint development of pan-marburg monoclonal antibody development with interagency partners. - Continue monoclonal antibody development for broad spectrum capabilities. - Continue developing core capabilities for NHP studies. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>			4.762	9.056	15.375
Title: 9) Viral Vaccines			6.943	6.289	9.401

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019	
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
<p>Description: Evaluate 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.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Complete licensure development of Zaire ebolavirus vaccine. - Continue development of an rVSV vaccine for Marburgvirus. Advance correlate of immunity validation for filovirus vaccines. - Continue manufacturing and formulation development and initiate efficacy and safety studies for advanced Alphavirus (WEVEE) vaccines. - Continue manufacturing and assay development for vesicular stomatitis virus (VSV) trivalent Filovirus vaccine with new manufacturer. - Evaluate ability of candidates to elicit sterilizing immunity in the mucosa. - Begin evaluation of candidate vaccines against arenavirus infection. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Complete assay qualification and validation for Ebola virus, Marburg virus, and alphavirus vaccines. - Continue formulation development of adjuvanted DNA Alphavirus vaccine and initiate efficacy studies in animal models. - Continue development of rVSV and DNA Marburg virus vaccines. - Continue evaluation of arenavirus vaccines in animal models. - Continue evaluation of rVSV Ebola vaccine duration of protection assessment. - Initiate stability and in vitro delivery studies of alphavirus DNA vaccine formulations. - Initiate evaluation of Filovirus aerosol pathology. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p>			
<p>Title: 10) Medical Diagnostics</p> <p>Description: Investigate medical diagnostics ubiquitous and comprehensive against chemical and biological threats (including NTAs, pharmaceutical-based agents, and toxins) by advancing diagnostic innovations. Aligning capabilities with the FDA pipeline and larger industry to ensure medical diagnostics can rapidly adapt to emerging threats and utilize emerging technologies while harvesting and synergizing the immense volume of diagnostic data.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Complete high sensitivity immunoassay and protein detection platforms for clinical samples. - Continue the development of assays and technologies for biological and chemical agent detection and characterization. 		-	32.532
			29.056

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Continue the development of a chemical diagnostic platform to diagnose exposure to chemical agents for use in forward field settings or at the point-of-need. - 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 samples. - Complete efforts and studies on host response biomarker classifiers (viral versus bacterial). <ul style="list-style-type: none"> - Continue incorporation of stability and pre-clinical studies for diagnostic assays in development to further support FDA pre-Emergency Use Authorization submissions. - Continue incorporation of stability and pre-clinical studies for diagnostic assays in development to further support pre-Emergency Use Authorization (EUA) submissions. - Continue multi-echelon diagnostic testing and assessments of novel point of need medical diagnostics in low resource settings and austere environments. - Initiate independent verification of sequencing protocols. - Initiate efforts to integrate or converge platform technologies to detect antimicrobial resistance/multidrug resistance. - Initiate the investigation for designing biomarker verification/validation methods and activities. - Initiate efforts to investigate the use of machine learning to develop diagnostic assays and/or predict assay erosion. <p>FY 2020 Plans:</p> <p>Biological:</p> <ul style="list-style-type: none"> - Complete development of rapid quantitative in-situ protein and gene expression platform technologies for host response. - Complete effort to develop and validate a lateral flow immunoassay for Burkholderia. - Complete optimization and enhancement of updated bioinformatics platform to support genomic and clinical (biomedical) informatics modularity. - Continue the development of diagnostic assays and technologies for biological threat agent identification, detection, and characterization. - Continue verification and testing performance of biomarker assays and reagents for point-of-need diagnostic platforms. - Continue multi-echelon diagnostic testing and assessments of novel point of need medical diagnostics in low resource settings and austere environments. - Continue to optimize pipelines to improve unbiased pathogen discovery and/or detection in clinical samples. - Continue incorporation of stability and pre-clinical studies for diagnostic assays in development to further support FDA pre-Emergency Use Authorization (pre-EUA) submissions. - Continue developing point-of-need diagnostic platforms with host biomarker diagnostic assays and testing performance. - Continue limited investigation of high sensitivity immunoassay and protein detection platforms for clinical samples in support of the development of a future protein-based diagnostic system. 					

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
<ul style="list-style-type: none"> - Continue efforts to investigate the use of artificial intelligence, machine learning, or deep learning to develop diagnostic assays and/or predict assay erosion. - Continue effort with Republic of Korea (RoK) on new Project Agreement to develop diagnostic platforms against biological threat agents of interest on the Korean peninsula. - Initiate investigations into building a core capability at a DoD laboratory to develop the first FDA pre-Emergency Use Authorization (pre-EUA) diagnostic assay for use on a next generation sequencing platform. - Initiate establishments of pipelines, workflows, and methodologies to develop complementary diagnostics. <p>Chemical:</p> <ul style="list-style-type: none"> - Continue the development of diagnostic assays and technologies for chemical threat agent identification, detection, and characterization. - Continue the development of a chemical diagnostic platform to diagnose exposure to chemical threat agents in forward field settings or at the point-of-need. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. This program subsumes TM3 (Techbase Med Defense) Assays and Reagents and TM3 (Techbase Med Defense) Diagnostic Device Platform in FY19.</p>				
<p>Title: 11) Chemical Therapeutics</p> <p>Description: Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to CWAs. This effort involves the development of neuroprotectants, anticonvulsants, and improved therapies for brain enzyme reactivation. Supports eventual FDA licensure of new compounds or to identify licensed products for use in the treatment of chemical warfare casualties.</p> <p>FY 2019 Plans:</p> <ul style="list-style-type: none"> - Employ optimized real-time microdialysis system to support therapeutic candidate analysis and development. - Continue using proof-of-concept in vivo experiments to measure neuroprotective effects of known and novel compounds. - Continue maintaining the ADMET CoE to ensure capability for development and supporting regulatory science to facilitate FDA licensure of chemical therapeutics. - Initiate advanced development of lead therapeutic candidates. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Complete proof-of-concept in vivo experiments to measure neuroprotective effects of known and novel compounds. - Continue using real-time microdialysis system to support therapeutic candidate analysis and development. - Continue advanced pre-clinical development of lead therapeutic candidates. <p>FY 2019 to FY 2020 Increase/Decrease Statement:</p>		0.387	1.884	2.360

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program										Date: March 2019		
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 2018	FY 2019	FY 2020
Increase due to change in program/project technical parameters.												
Title: 12) Medical Diagnostics Response Capability Development										-	-	10.500
Description: Investigate medical diagnostics ubiquitous and comprehensive against chemical and biological threats (including] NTAs, pharmaceutical-based agents, and toxins) by advancing diagnostic innovations. Aligning capabilities with the FDA pipeline and larger industry to ensure medical diagnostics can rapidly adapt to emerging threats and utilize emerging technologies while harvesting and synergizing the immense volume of diagnostic data.												
FY 2020 Plans:												
Biological:												
- Continue efforts to integrate or converge platform technologies to detect antimicrobial resistance/multidrug resistance (AMR/ MDR) and pathogen identification into one platform.												
- Initiate the advancement of next-generation sequencing for use as a medical diagnostic capability.												
- Initiate the development of the In-vitro Affinity Diagnostic System (IADS) platform that will complement the currently fielded molecular-based diagnostics system.												
Chemical:												
- Initiate diagnostics capability to support Defense Laboratory Network (DLN) efforts against chemical warfare agent exposure.												
FY 2019 to FY 2020 Increase/Decrease Statement:												
Increase due to change in program/project technical parameters. Increase for CBDP Support to Bio-Incident Response.												
Accomplishments/Planned Programs Subtotals										92.231	88.188	120.526
C. Other Program Funding Summary (\$ in Millions)												
Line Item	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
• MB4: MEDICAL BIOLOGICAL DEFENSE (ACD&P)	71.070	65.209	48.166	-	48.166	75.343	70.991	78.526	73.550	Continuing	Continuing	
• MC4: MEDICAL CHEMICAL DEFENSE (ACD&P)	4.666	2.388	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	7.054	
• MB5: MEDICAL BIOLOGICAL DEFENSE (EMD)	130.240	117.331	119.227	-	119.227	97.501	71.221	78.435	82.815	Continuing	Continuing	
• MC5: MEDICAL CHEMICAL DEFENSE (EMD)	58.419	57.545	62.051	-	62.051	64.331	56.641	28.559	26.976	Continuing	Continuing	

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program			Date: March 2019
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)	

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

<u>Line Item</u>	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020</u> <u>Base</u>	<u>FY 2020</u> <u>OCO</u>	<u>FY 2020</u> <u>Total</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• MB7: <i>MEDICAL BIOLOGICAL DEFENSE (OP SYS DEV)</i>	11.195	9.021	3.720	-	3.720	3.365	2.887	2.179	7.552	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

E. Performance Metrics

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program										Date: March 2019		
Appropriation/Budget Activity 0400 / 3					R-1 Program Element (Number/Name) PE 0603384BP / CHEMICAL/BIOLOGICAL DEFENSE (ATD)				Project (Number/Name) TT3 / TECHBASE TECHNOLOGY TRANSITION			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
TT3: TECHBASE TECHNOLOGY TRANSITION	-	11.352	10.191	10.982	-	10.982	11.011	11.004	11.003	11.001	Continuing	Continuing

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 that could significantly improve Warfighter capabilities in preparation for transition of mature chemical and biological (CB) defense technologies to advanced development programs.

Individual efforts in this project include:

- These programs offer the opportunity to identify and efficiently mature emerging technologies, reduce risks, and finalize engineering and integration efforts.
- These 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 the four primary thrust areas of Sense, Shape, Shield, and Sustain, with an emphasis on Integrated Early Warning. Integrated Early Warning is conducted through a coordinated program approach focused on layering Chemical and Biological Detection technologies and integrating CB threat indicators to provide combination of awareness and understanding that facilitates effective (timely) decision making so the force can continue military operations and achieve mission success in a CBRN environment.

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

	FY 2018	FY 2019	FY 2020
Title: 1) Experiment & Technology Demonstrations	11.352	10.191	10.982
Description: Utilize Concept Experimentation, Warfighter Utility Assessments and Advanced Technology Demonstrations (ATDs) to demonstrate the maturity and potential of advanced technologies across the Sense/Shape/ Shield/Sustain spectrum for enhanced military operational capability or cost effectiveness.			
FY 2019 Plans:			
- Continue situational understanding at the tactical level and initiate situational understanding at the operational level for the comprehensive IEW ATD.			
- Continue S&T integration activities for CB sensor technologies onto mobile platforms as part of the second phase of the comprehensive early warning ATD. Demonstrate integration of wearable sensors as part of the comprehensive early warning ATD. To be integrated on CBRN Sensor Integration on Robotic Platforms (CSIRP). Demonstrate prototype end-to-end early warning capability at an OCONUS area of responsibility.			

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Exhibit R-2A, RDT&E Project Justification: PB 2020 Chemical and Biological Defense Program		Date: March 2019	
Appropriation/Budget Activity 0400 / 3	R-1 Program Element (Number/Name) PE 0603384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (ATD)</i>	Project (Number/Name) TT3 / <i>TECHBASE TECHNOLOGY TRANSITION</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
<ul style="list-style-type: none"> - Continue transition activities with advanced development and associated JPM program efforts supporting the CBDP IEW focus area. - Continue to conduct Rapid Military Utility Assessments (RMUAs) and field experiments to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. - Continue Demonstration Concept Development and Experimentation activities in support of Early Warning and Integrated & Layered Defense. <p>FY 2020 Plans:</p> <ul style="list-style-type: none"> - Continue situational understanding at the tactical level and initiate situational understanding at the operational level for the comprehensive IEW ATD. - Continue S&T integration activities for CB sensor technologies onto mobile platforms and transition to JPEO CBRN Sensor as part of the second phase of the comprehensive early warning ATD. To be integrated on CBRN Sensor Integration on Robotic Platforms (CSIRP). Demonstrate integration of wearable sensors as part of the comprehensive early warning ATD. Demonstrate service specific prototype end-to-end early warning capability at an OCONUS area of responsibility. - Continue transition activities with advanced development and associated JPM program efforts supporting the CBDP IEW focus area. - Continue to conduct Warfighter Utility Assessments to assess early technology capability contributions, in collaboration with the CBDP Joint Combat Developer. - Continue concept experimentation activities in support of Early Warning and Integrated & Layered Defense. <p>FY 2019 to FY 2020 Increase/Decrease Statement: Minor change due to routine program adjustments.</p>			
Accomplishments/Planned Programs Subtotals		11.352	10.191
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
N/A			
E. Performance Metrics			
N/A			