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Exhibit R-2, RDT&E Budget Item Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

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| 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>Chemical and Biological Defense Program - Advanced Development</i> |
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| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | 0.000 | 191.695 | 226.225 | 267.073 | 0.000 | 267.073 | 273.070 | 276.331 | 259.918 | 263.525 | Continuing | Continuing |
| UN3: <i>Understand (ATD)</i> | - | 0.000 | 68.415 | 83.825 | 0.000 | 83.825 | 81.392 | 87.384 | 73.515 | 71.015 | Continuing | Continuing |
| PT3: <i>Protect (ATD)</i> | - | 0.000 | 32.113 | 29.261 | 0.000 | 29.261 | 48.969 | 42.794 | 46.159 | 52.581 | Continuing | Continuing |
| MT3: <i>Mitigate (ATD)</i> | - | 0.000 | 86.157 | 100.791 | 0.000 | 100.791 | 89.511 | 91.704 | 85.795 | 85.480 | Continuing | Continuing |
| EN3: <i>Enabling Investments (ATD)</i> | - | 0.000 | 39.540 | 43.196 | 0.000 | 43.196 | 43.198 | 44.449 | 44.449 | 44.449 | Continuing | Continuing |
| ET3: <i>Emerging Threats (ATD)</i> | - | 0.000 | 0.000 | 10.000 | 0.000 | 10.000 | 10.000 | 10.000 | 10.000 | 10.000 | Continuing | Continuing |
| CB3: <i>Chemical Biological Defense (ATD)</i> | - | 28.484 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 28.484 |
| NT3: <i>Non-Traditional Agents Defense (ATD)</i> | - | 10.843 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 10.843 |
| TM3: <i>Techbase Medical Defense (ATD)</i> | - | 144.779 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 144.779 |
| TT3: <i>Technology Transition (ATD)</i> | - | 7.589 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 7.589 |

A. Mission Description and Budget Item Justification

This program element (PE) resources Advanced Technology Development across the Understand, Protect, Mitigate, and Enabling Investments portfolios. Chemical and Biological Defense Program (CBDP) investments provide an integrated, layered capability to enable Countering Weapons of Mass Destruction (CWMD) missions ranging from combat operations to Department of Defense (DoD) support to domestic incident prevention and response. The Projects in this PE demonstrate technologies supporting the transition to advanced component development for physical capabilities, which cover chemical and biological (CB) detection, situational awareness and effects modeling, and protection and hazard mitigation. FY24 funding accelerates characterization and situational awareness of emerging biothreats and accelerates delivery of improved protection from and mitigation of biothreats, including rapid repurposing of available therapeutics and development of new vaccines.

Individual Projects include:

- Understand (UN3): Demonstration of enhanced chemical detection capabilities for aerosols and non-traditional agents, expanded capabilities for biosurveillance in pathogen detection and diagnosis, produce biological diagnostic arrays and reagents and diagnostic device platforms.
- Protect (PT3): Production of pretreatment candidates for bacterial, viral, and toxin threats.

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- Mitigate (MT3): Production of therapeutic candidates for bacterial, viral, and toxin threats.
- Enabling Investments (EN3): Demonstrations of CB defense technologies, including biological detection, chemical detection, and decontamination, including non-traditional agents. Continued efforts to enhance the military operational capability, concepts of operation, and WMD elimination.
- Emerging Threats (ET3): identify and develop scientific solutions or to modernize capabilities that allow for a more rapid response to emerging threats.
- Chemical Biological Defense (CB3), Non-Traditional Agents (NTA) Defense (NT3), Techbase Medical Defense (TM3), and Technology Transition (TT3) are no longer active FY24 Projects due to budget restructuring.

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

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

| B. Program Change Summary (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 197.824 | 238.407 | 248.071 | - | 248.071 |
| Current President's Budget | 191.695 | 226.225 | 267.073 | - | 267.073 |
| Total Adjustments | -6.129 | -12.182 | 19.002 | - | 19.002 |
| • Congressional General Reductions | - | -0.182 | | | |
| • Congressional Directed Reductions | - | -17.000 | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | 5.000 | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | -3.365 | - | | | |
| • SBIR/STTR Transfer | -2.764 | - | | | |
| • Other Adjustments | - | - | 19.002 | - | 19.002 |

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

Project: MT3: *Mitigate (ATD)*

| | FY 2022 | FY 2023 |
|--|----------------|----------------|
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

Congressional Add: *Broad Spectrum Small Molecule Anti-viral Development*

Congressional Add Subtotals for Project: MT3

Congressional Add Totals for all Projects

| | FY 2022 | FY 2023 |
|--|---------|---------|
| | - | 5.000 |
| | - | 5.000 |
| | - | 5.000 |

Change Summary Explanation

Funding: FY 2022 (-\$3.365 Million): Below threshold reprogramming to support Advanced Emerging Threat Defense efforts in Advanced Component Development & Prototypes, Budget Activity 4, and reprogrammed prior year execution balances to RDT&E Management Support, Budget Activity 6 in support of the Departments higher priorities.

FY 2022 (-\$2.764 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY 2023 (-\$0.182 Million): Congressional General Reductions to support Federally Funded Research and Development Centers (FFRDCs).

FY 2023 (-\$17.000 Million): Congressional Directed Reductions.

FY 2023 (+\$5.000 Million): Congressional Add for broad spectrum small molecule anti-viral development.

FY 2024 (+\$19.002 Million): Increase for Chemical Warfare Defense Prophylaxis and Therapeutics and CBRN Warning and Decision Support efforts (+\$12.033 Million), to expand early warning through wastewater surveillance capabilities (+\$5.700 Million), and Departmental inflation rate adjustments (+\$1.269 Million).

Schedule: N/A

Technical: N/A

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| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|------------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| UN3: <i>Understand (ATD)</i> | - | 0.000 | 68.415 | 83.825 | 0.000 | 83.825 | 81.392 | 87.384 | 73.515 | 71.015 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

The Understand Advanced Technology Development (ATD) Project supports freedom of maneuver and informs commanders' decisions by predicting, locating, identifying, analyzing, and warning of chemical and biological (CB) hazards. In FY 2023, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. UN3 efforts in FY 2022 remain in Projects CB3, NT3, and TM3. This restructuring provided standardization and alignment across CBDP research, development and acquisition efforts.

Thrust Areas included in this Project are:

- (1) Chemical, Biological, Radiological, and Nuclear (CBRN) Battlespace Sensing, Alerting & Response
- (2) CBRN Decision Aids
- (3) CBRN Situational Awareness
- (4) Battlefield Readiness
- (5) Chemical Diagnostics
- (6) Clinical Evaluation
- (7) Diagnostic Building Blocks
- (8) Emerging Threats
- (9) Emerging and Enhanced Biothreat Sensing
- (10) Distributed CB Reconnaissance
- (11) Expeditionary Analytical Toolkit (ExAnT)
- (12) Unconventional Detection Modalities
- (13) Technical Surprise
- (14) Unattended Perimeter Monitoring

CBRN Battlespace Sensing, Alerting & Response: Development of algorithms that generate and disseminate warning to personnel in time to prevent exposure to or limit the impact of CBRN threats. This thrust area conducts data collection trials to support algorithm development; leverage Artificial Intelligence (AI) to identify key indicators, combinations of indicators, and sensing modalities to reduce false alarms and predict the likelihood of exposure; explore remote and contactless monitoring and analysis for application in Warfighter chemical and biological threat exposure alerting. Efforts include additional investments in enhanced biodefense and pandemic preparedness.

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| <p>CBRN Decision Aids: Providing tools that assess risk from CBRN hazards and identify courses of action to limit impact. This thrust area permits connectivity, enabling the dynamic discovery, querying, and control of sensors through standard protocols; allow for dynamic discovery and integration between networked devices at the tactical edge to enable sharing of information and capabilities across connected components. Efforts include additional investments in enhanced biodefense and pandemic preparedness.</p> <p>CBRN Situation Awareness: Providing operationally relevant context to CB-specific phenomena data to ensure the Joint Force is able to characterize new CB hazards and mitigate their effects on mission success. This thrust area provides the analytic framework to determine optimal defense postures by extrapolating scientific data generated during the course of technology development and hazard assessment data into an assessment to help inform operational utility. Efforts include additional investments in enhanced biodefense and pandemic preparedness.</p> <p>Battlefield Readiness: Provides innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provides diagnosis at lower roles of care. Develops field forward medical diagnostics to provide multiplexed detection of biological and toxin threats and leverages immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.</p> <p>Chemical Diagnostics: Discovers innovative and integrated capabilities that are able to diagnose threats across the chemical spectrum and enhance force protection by investing in diagnostics for exposure to traditional and nontraditional Chemical Warfare Agents (CWA), including pharmaceutical based agents. Efforts include coordinating with Threat Agent Science and the Intelligence Community and to understand the chemical threat space.</p> <p>Clinical Evaluation: Provides independent verification and validation of diagnostic tests in real world patients to decrease development costs, collecting initial clinical data sets to support pre-submission discussions with the Food and Drug Administration (FDA). De-risks diagnostic platform development through third party, real world, and austere environment testing and evaluation prior to transition and establishes clinical and performance parameters therefore de-risking diagnostic platforms through real world populations.</p> <p>Diagnostic Building Blocks: Develops foundational capabilities for the entire diagnostics portfolio; invests in innovative, cutting-edge technologies to improve the development pipeline for diagnostics; and exploits areas in artificial intelligence synthetic biology and machine learning to develop novel and rapid diagnostic tests for utilization. Efforts accelerate assay development timelines and optimize test parameters by leveraging novel concepts and tools that readily allow a pivot to assay development for emerging threats.</p> <p>Emerging Threats: Invests in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure, to greatly advance efficacy rates and turnaround time for Warfighter wellness. Efforts focus on better preparing for surprise by developing diagnostic systems that leverage novel approaches to characterize pathogens or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample.</p> <p>Emerging and Enhanced Biothreat Sensing: Establishes a capability to rapidly develop advanced, agile, pathogen-agnostic laboratory and field forward detection capabilities to detect emerging and enhanced biological threats across all force echelons (presumptive, field confirmatory, theater validation, and definitive identification).</p> | | |

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Further, multiple biological measurements will be used to modernize laboratory capabilities and leverage synthetic biology methods and tools to deliver enhanced biothreat sensing/detection capabilities to the Joint Force.

Distributed CB Reconnaissance: Enhances early warning and situational awareness of CB threats while reducing potential Warfighter exposure using distributed CB reconnaissance tools to include low-cost point sensors and sensing/collection systems for unmanned platforms. Efforts include developing threat sensing and sampling payloads for manned and unmanned aerial and ground platforms to enhance early warning and situational awareness of CB threats.

Expeditionary Analytical Toolkit (ExAnT): Provides general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.

Unconventional Detection Modalities: Develops disruptive technologies to identify unknown or emerging chemical threats and develops chemical sensors that can operate in complex threat environments with high fidelity. Efforts include utilizing machine learning and other advanced computational tools to increase detection and identification accuracy, reduce false alarms, and enable mapping of hazardous locations to support integrated early warning (IEW) capabilities.

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

Unattended Perimeter Monitoring: Invests in efforts supporting Integrated Early Warning and Integrated Layered Defense by establishing a layered defense capability through developing and implementing automated and integrated technologies enabling unattended monitoring for biothreats.

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>Title: 1) CBRN Battlespace Sensing, Alerting, and Response</p> <p>Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. Expand on the development of predictive CB exposure algorithms based on non-invasively collected human biomarkers. Improve on the applicability and efficacy of these algorithms focusing on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. Enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. Matured algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue the improvement of algorithms that leverage non-invasive based physiological data to provide early warning of chemical and biological threats and/or exposure. | - | 5.171 | 4.500 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue the advancement of standoff physiological monitoring capabilities.</p> <p>- Leverage a data and AI platform that supports access to harmonized physiological status monitoring data and support development and validation of models to continue to develop predictive algorithms aimed at the rapid response to Emerging Threats.</p> <p>FY 2024 Plans:</p> <p>- Continue the improvement of algorithms that leverage non-invasive based physiological data to provide early warning of chemical and biological threats and/or exposure.</p> <p>- Continue the advancement of standoff physiological monitoring capabilities.</p> <p>- Expand and further develop a data and Artificial Intelligence (AI) platform to support the access to harmonized physiological status monitoring data and development and validation of models in order to continue to develop predictive algorithms for the rapid response to Emerging Threats.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> <p>Minor change due to routine program adjustments.</p> | | | | |
| <p>Title: 2) CBRN Decision Aids</p> <p>Description: Unencumber the warfighter at the tactical edge by continuing to development and fielding of CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. Develop a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards. Develop of Autonomous Asset Guidance for use in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize Autonomous Asset use and reduce the burden incurred by the warfighter in order to operate them. Incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> <p>FY 2023 Plans:</p> <p>- Continue developing new decision support plug-ins for integration with Tactical Assault Kit (TAK), including the Android, web, Windows OS, and virtual and augmented reality versions, to further enhance the TAK infrastructure and cross-community tools and develop a rapid and iterative software capability.</p> <p>- Complete development of Graphical Processing Unit (GPU)-based faster-than-real-time, high resolution hazard prediction modeling capabilities and continue user testing.</p> <p>- Finalize the development of approaches to translate raw sensor data and publish to a common standard.</p> <p>FY 2024 Plans:</p> | | - | 3.000 | 3.500 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue developing new decision support plug-ins for integration with TAK, including the Android, web, Windows OS, and virtual and augmented reality versions, to further enhance the TAK infrastructure and cross-community tools and develop a rapid and iterative software capability.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 3) CBRN Situational Awareness</p> <p>Description: To enhance chemical and biological (CB) Situational Awareness, Science & Technology will expand the types of CB threats that can be modeled with hazard assessment capabilities to include those from fixed-wing and rotary-wing drones of interests and allow for airborne CB releases from single drones and swarms to be modeled. Leverage Virtual Reality (VR) and Augmented Reality (AR) technologies to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems. Enhance hazard modeling by creating a seamless indoor- to-outdoor transport and dispersion (T&D) modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. Leverage new state-of-the-art computational fluid dynamics modeling techniques and their use of computing resources to increase both modeling speed and accuracy. Develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Develop epidemiological models that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents. Leverage Threat Agent Science (TAS) data to enhance modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents, providing the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue configuration management of science and technology prototype for transition of upgraded capabilities. - Continue improvement of performance enhancements for T&D models, particularly for urban environments. - Continue the development of comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. - Continue to enhance CB situational awareness capabilities for integration into Head up Display (HUD) technologies for tactical use. - Build out pipelines for ingestion and storage of disparate chemical and biological threat datasets and advanced analytic development to support the CBDP medical enterprise. <p>FY 2024 Plans:</p> | | - | 3.888 | 6.690 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <ul style="list-style-type: none"> - Complete development of a digital environment prototype for science and technology software modernization using a Development, Security, and Operations (DevSecOps) framework. - Continue improvement of performance enhancements for T&D models, particularly for urban environments and for hazard release from drone platforms and alternate types of delivery mechanisms. - Continue the development of comprehensive infectious disease epidemiological modeling applications for disease prediction, forecasting, medical planning and treatment. - Continue to enhance CB situational awareness capabilities for integration into Heads up Display (HUD) technologies for tactical use. - Continue work to ingest and store disparate chemical and biological threat datasets and advanced analytic development to support the CBDP medical enterprise. - Expedite the development of a CB Defense Digital Laboratory capability encompassing a DevSecOps environment for end-to-end AI/ML data analysis, model development and training, and agile software development. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 4) CBRN Battlespace Surveillance, Alerting & Response - Enhanced Biodefense (ENBD)</p> <p>Description: Focus on a passive, wearable, contactless screening capability would greatly enhance the Warfighters' ability to seek medical treatment at the earliest indication of exposure. This area includes data collection and analysis of exposure data; competitive prototyping to further develop algorithms that are able to non-invasively identify afflicted personnel and inform courses of action, prior to the onset of symptoms; expansion of efforts to develop analytic resources for early warning/decision support; and S&T for an advanced, integrated cloud based data environment to store a dynamic knowledge base of biothreat characteristics.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Examine feasibility of isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. - Leverage competitive prototyping to explore and evaluate alternative concepts for providing remote sensing and/or minimally- and non-invasive techniques to enhance our ability to quickly identify afflicted personnel and inform courses of action, ideally prior to the onset of symptoms. - Development of an advanced, integrated cloud based data environment to store a dynamic knowledge base of biothreat characteristics; capability would support automated data ingestion, collection, curation, search, and advanced analytics of data. <p>FY 2024 Plans:</p> | | - | 2.400 | 2.500 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>- Continue to isolate and identify indicators of respiratory infection that can be used in determining severity of infection, and predicting return to mission readiness after exposure.</p> <p>- Continue competitive prototyping to evaluate alternative concepts for providing remote sensing and/or minimally and non-invasive techniques to enhance our ability to quickly identify afflicted personnel and inform courses of action, ideally prior to the onset of symptoms.</p> <p>- Continue the development and expansion of an advanced, integrated cloud based data environment to store a dynamic knowledge base of biothreat characteristics; capability would support automated data ingestion, collection, curation, search, and advanced analytics of data.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | |
| <p>Title: 5) CBRN Decision Aids - Enhanced Biodefense (ENBD)</p> <p>Description: Focus on improved solutions for comprehensive biothreat characterization in support of CBDP biodefense modernization goals, to include leveraging a cloud based data environment of biothreat characteristics, data sources, repositories created and curated under the CBRN Battlespace Sensing, Alerting, and Response thrust area. Cloud based data environment will be leveraged and data streams will be translated into actionable information for transmission to and use on end-user devices (EUDs).</p> <p>FY 2024 Plans: -Explore and initiate efforts that will utilize data streams from a cloud based data environment to provide actionable information about biological threats and exposures on EUDs.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p> | - | - | 1.000 |
| <p>Title: 6) CBRN Situational Awareness - Enhanced Biodefense (ENBD)</p> <p>Description: Focus on exploring solutions for comprehensive biothreat characterization in support of CBDP biodefense modernization goals, including the development of data analytics using machine learning and artificial intelligence (ML/AI) and efforts to provide a suite of analytic tools for biological threat agent modeling, forecasting, and prediction to determine optimal defense postures. Utilize scientific data generated during the course of technology development and hazard assessment data) to help inform operational utility. Develop epidemiological models that quantify risk and visualize mission operational impacts accounting for medically relevant inputs from exposure to and spread of CB threat agents of relevance to DoD.</p> <p>FY 2023 Plans: - Expand development of analytic tools for biological threat agent surveillance, modeling, forecasting, and prediction.</p> | - | 3.000 | 2.500 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Accelerate and expand efforts to develop data analytics using ML/AI to predict individual warfighter susceptibility to acute CB agent exposure based on advanced omics, epigenetics, host immune responses, and wearables data sources.</p> <p>- Explore feasibility of mathematical models for innate immune recognition based on clinical data and prediction of signature patterns associated with bacterial vs. viral pathogens.</p> <p>FY 2024 Plans:</p> <p>- Continue the development of analytic tools for biological threat agent surveillance, modeling, forecasting, and prediction.</p> <p>- Continue efforts to develop data analytics using ML/AI to predict individual warfighter susceptibility to acute CB agent exposure based on advanced omics, epigenetics, host immune responses, and wearables data sources.</p> <p>- Continue to explore mathematical models for innate immune recognition based on clinical data and prediction of signature patterns associated with bacterial vs. viral pathogens.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 7) Battlefield Readiness</p> <p>Description: Develop platforms to prepare the Warfighter with rapid and easy to use diagnostics tests to make sure they are healthy and ready for movement. Platforms developed with affinity-based identification of either pathogen or host response to the pathogen may leverage immunodiagnostics to identify specific targets using antibodies, or explore other innovative approaches. This will enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. Investments in this area will provide capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care.</p> <p>FY 2023 Plans:</p> <p>- Complete the development and evaluation of a customizable, lightweight, comfortable, in ear wearable device (EWD) and algorithms to detect disease onset by monitoring a Warfighter's health state.</p> <p>- Complete the development of vertical flow assay technologies that are rapid, capable of multiplexing, portable, and may result in a faster sample to answer and more sensitive detection level than traditional lateral flow diagnostics.</p> <p>- Complete the program to identify biological indicators that predict disease severity, which will lead to the development of a diagnostic that alerts medical personnel that a patient's condition may worsen or require immediate intensive care.</p> <p>- Continue a wearable effort for developing and testing a microneedle-based patch intended to screen for the presence of a viral or bacterial infection, this focus on minimally invasive testing techniques along with easy to use wearables will further support DoD mission readiness.</p> | | - | 6.700 | 5.085 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue the development of a POC diagnostic platform that can provide the Warfighter pre-symptomatic diagnosis of infection, irrespective of whether the underlying pathogens are viral, bacterial, or parasitic.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue investigating minimally invasive testing methods and reduce diagnostic windows, even to pre-symptomatic identification. - Continue the development of a Point of Contamination (POC) diagnostic platform, capable of pre-symptomatically diagnosing infection within minutes and transition technology to Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense's (JPEO-CBRND) Advanced Differential Diagnostics (ADD) program. Pre-symptomatic evaluation will enable forces to determine personnel who are ideal candidates for troop movements or basic training. - Continue the development of a non-invasive diagnostic platform that can predict severity of disease which will enable logistical and resource optimization as well as quicker return of duty for a majority of patients. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 8) Chemical Diagnostics</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional CWAs, including pharmaceutical based agents. Coordinate with the Intelligence Community (IC) to understand the chemical threat space, adapting capabilities to meet the need.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue efforts that expand the capability of wearable devices from an alert to an U.S. Food & Drug Administration (FDA) approved diagnostic platform that can detect a chemical threat and allow a physician to diagnose and determine a treatment strategy for exposure to traditional/ nontraditional chemical agents. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue efforts that expand the capability of wearable devices from an alert to an FDA-approved diagnostic platform that can detect a chemical threat and allow a physician to diagnose and determine a treatment strategy for exposure to traditional/ nontraditional chemical agents. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p> | | - | 1.914 | 1.695 |
| <p>Title: 9) Clinical Evaluation</p> | | - | 1.914 | 0.848 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
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| <p>Description: Optimize the diagnostic development pathway by incorporating independent testing and evaluation for more informed prototype transition prior to advanced development. Investments in this area allow e evaluation of diagnostic platforms through real world, austere environment testing. This area maintains access to research sites that offer native populations exposed to diseases of interest that would affect the warfighter in battlefield settings, and provides the ability to acquire novel technologies and provide analytical testing, evaluation, and reach back support for technologies already fielded.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating. - Initiate independent third-party testing - to establish clinical and performance parameters to evaluate diagnostic platforms through real world, austere environment testing and evaluation prior to transition. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue to maintain the capability to access clinical samples for infectious diseases of interest, and collaborate with sites around the world where diseases of concern are circulating. - Continue independent third-party testing - to establish clinical and performance parameters to evaluate diagnostic platforms through real world, austere environment testing and evaluation prior to transition. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p> | | | |
| <p>Title: 10) Diagnostic Building Blocks</p> <p>Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats in days instead of weeks.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate field validation studies for diagnostics prototypes using synthetic binders and evaluate performance against current gold standard diagnostic methods. - Continue efforts to collect the baseline data required for future development of a whole breath diagnostic platform use of breath as a non-invasive sampling mechanism offers Warfighters little-to-no interruption to mission activities and provides the opportunity for earlier diagnosis/indication of infection or chemical exposure. | - | 4.786 | 5.934 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue executing data transitions for the development of diagnostic assays to support vaccine and countermeasure development efforts.</p> <p>- Complete a joint effort with CBDP Components to establish an assay development and manufacturing process that would allow DoD laboratories to be authorized assay developers, enabling the DoD to develop assays against emerging threats and diseases to quickly be functionalized for the fielded Next Generation Diagnostics System (NGDS) 2 Man Portable Diagnostic System (MPDS) platform.</p> <p>FY 2024 Plans:</p> <p>-Continue field validation studies for diagnostics prototypes using synthetic binders and evaluate performance against current gold standard diagnostic methods and integrate enzymes to create inexpensive, on-demand, diagnostics with reduced logistical burdens.</p> <p>-Continue efforts to collect the baseline data required for future development of a whole breath diagnostic platform the use of breath as a non-invasive sampling mechanism offers warfighters little-to-no interruption to mission activities and provides the opportunity for earlier diagnosis/indication of infection or chemical exposure.</p> <p>- Initiate efforts to identify and establish testing methods utilizing low to minimally invasive clinical matrices. Matrices like breath, sweat or interstitial fluid could significantly expand field-forward testing abilities and minimize requirements for trained personnel to collect and administer testing.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 11) Emerging Threats</p> <p>Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.</p> <p>FY 2023 Plans:</p> <p>- Complete efforts to address challenges in small molecule toxin diagnosis at the point of contamination (POC) and initiate validation of these prototypes for potential use as a threat agnostic capability to enable field-forward responses to emerging threats.</p> | | - | 2.828 | 3.391 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Complete the development of a universal blood sample preparation platform to be compatible with several diagnostic systems, improving the speed of sample preparation tools at low pathogen concentrations (i.e. pre-symptomatic levels) is one of the biggest challenges holding back diagnostics in point-of-care, outbreak, and remote testing scenarios.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Initiate efforts to identify novel platforms that are capable of identifying broad classes of toxins in complex matrices. These platforms will ideally enable the diagnosis of exposure to toxins as well as other biological threats, resulting in a broad-spectrum capability in the hands of the warfighter. - Begin preliminary research efforts to diagnose biological threats that are truly unknown but could cause genomic or proteomic changes in infected individuals. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 12) Emerging and Enhanced Biothreat Sensing</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Expand early warning through wastewater surveillance capabilities to enable detect to warn capability and identification of unknown biological threats in Total Force populations. - Initiate technology to deliver capabilities to detect any pathogen, including engineered bioweapons. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Additional investment to advance the overarching goals aligned with the 2022 National Biodefense Strategy and Implementation Plan (NBS).</p> | | - | - | 5.700 |
| <p>Title: 13) Distributed Chemical Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete aerosol microsensor development. - Development toward a deployable microsensor development pipeline and enhance sensor integration efforts. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue development toward a deployable microsensor development pipeline and enhance sensor integration efforts. | | - | 3.157 | 3.176 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| - Initiate efforts to modernize capabilities to reduce false alarms and increase sensitivity and specificity. | | | | |
| FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments. | | | | |
| Title: 14) Expeditionary Analytical Toolkit (ExAnT) - Chemical Detection | | - | 14.757 | 17.269 |
| Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards. | | | | |
| FY 2023 Plans: | | | | |
| - Commence transition stand-off detector prototypes that identify and alert to chemical hazards to Proximate Chemical Agent Detector (PCAD) Program of Record. | | | | |
| - Continue development toward detection prototypes to address pharmaceutical based agent (PBA) and other emerging threats. | | | | |
| - Continue the development of sensor technologies against non-traditional threats of concern to develop class-based detection and reduce reliance on known threat libraries. | | | | |
| FY 2024 Plans: | | | | |
| - Transition stand-off detector prototypes that identify and alert to chemical hazards to PCAD Program of Record. | | | | |
| - Continue development toward detection prototypes to address PBA and other emerging threats. | | | | |
| - Continue the development of sensor technologies against non-traditional threats of concern to develop class-based detection and reduce reliance on known threat libraries. | | | | |
| FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters. | | | | |
| Title: 15) Unconventional Chemical Detection Modalities | | - | 1.485 | 2.443 |
| Description: Develop disruptive technologies to identify unknown or emerging chemical threats and develop chemical sensors that can operate in complex threat environments with high fidelity. This thrust area supports other thrust areas and as needed the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance). | | | | |
| FY 2023 Plans: | | | | |
| - Complete development and refinement of integrated photonics. | | | | |
| - Complete development and refinement of miniaturized Raman spectrometers. | | | | |
| - Complete development and refinement of machine learning algorithms for integrating disparate sensor feeds. | | | | |
| - Initiate library-less detection efforts to move towards threat agnostic detection and provide rapid-fielded capabilities to address emerging chemical threats. | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue development of state of the art size and speed of detection technologies that include advances in computational tools, Artificial Intelligence (AI)/Machine Learning (ML) to address the most difficult changes in chemical detection.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue pursuing advances in photonic integrated circuits by reducing size, weight and power of traditional photonic sensors but keeping the selectivity and sensitivity of a traditional sensor. - Incorporating early warning and threat mapping using ML/AI tools to aggregate and analyze sensor data in real-time. - Continuing library-less detection to surmount current sustainment limitations of library-based or analyte-specific chemical sensor to be updated to detect emerging threats. - Continue development in machine learning (ML) and artificial intelligence (AI) to make sensor detection faster with reduced false alarm rates. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 16) Battlefield Readiness - Biodefense Improvement Program</p> <p>Description: Provide non-invasive disease screening capabilities to rapidly respond to emerging biological threats and greatly enhance the warfighters ability to seek medical treatment at the earliest indication of exposure.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Expand development of Wearable technologies to evaluate customizable hardware and algorithms that detect warfighters autonomic- response to biological warfare agents, both natural and unnatural. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | - | - | 4.235 |
| <p>Title: 17) Diagnostic Building Blocks - Biodefense Improvement Program</p> <p>Description: Provide agile assay development capabilities aided by Artificial Intelligence (AI) to advance the speed and accuracy of diagnostic assay design, addressing a key functional capability needed for emerging biological threat response.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Expand the development of agile biological assays to reduce the design assay and increase assay quality to better respond to emerging biological threats. <p>FY 2024 Plans:</p> | | - | 1.500 | 1.347 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue the development of agile biological assays to reduce the design assay and increase assay quality to better respond to emerging biological threats.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | | |
| <p>Title: 18) Emerging and Enhanced Biothreat Sensing - Biodefense Improvement Program</p> <p>Description: Provide end users with a rapid assay capability (< 6 weeks from discovery of emerging/enhanced threat to delivery of the initial assay) that will be disruptive to current detection and diagnostic timelines. Eliminate the need to rely on single-source reagents to rapidly respond to emerging biological threat.</p> <p>FY 2023 Plans: - Accelerate assay development to provide rapid, agile, and scalable biodetection technology to quickly address emerging biological threats and allow the warfighter to use a highly-specific assay that is built to minimize logistics burden and is user-friendly.</p> <p>FY 2024 Plans: - Continue assay development to provide rapid, agile, and scalable biodetection technology to quickly address emerging biological threats and allow the warfighter to use a highly-specific assay that is built to minimize logistics burden and is user-friendly.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters.</p> | | - | 2.200 | 1.865 |
| <p>Title: 19) Emerging Threats - Biodefense Improvement Program</p> <p>Description: Expand on agnostic disease screening and sensing capabilities for emerging biological threats.</p> <p>FY 2023 Plans: - Expand investments in agnostic sensing/screening capabilities for multiple sample types and environments that are end user-friendly and can be deployed in the field.</p> <p>FY 2024 Plans: - Continue prototype development investments in agnostic sensing/screening capabilities for multiple sample types and environments that are end user-friendly and can be deployed in the field.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | - | 1.000 | 3.170 |
| <p>Title: 20) Technical Surprise - Biodefense Improvement Program</p> | | - | 3.000 | 0.500 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>Description: Technical Surprise assesses technological advancements for potential implications to the threat space, including agent use and release. Technical Surprise includes horizon scanning to identify potential areas of concern as well as conducts technical assessments of emerging technological advancements (e.g. biotechnology, artificial intelligence, machine learning, quantum computing). This program develops capabilities to evaluate and assess technical enhancements that may alter the nature or magnitude of a threat agent. The technical surprise program will be evaluating technologies and convergence of technologies that improve the ease of threat use and make threats more likely to survive being released. The program will identify the limitations and barriers associated with synthetic biology and assess the implications. And finally, these efforts will identify and assess former technology hurdles that have been lowered or overcome and assess implications of increasing potential threat.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Identify and assess technological advancements that will impact the biological threat space, including potential threats that have implications to biological defense capabilities. - Use horizon scanning capability to provide situational awareness in assessing technological growth and convergence that can affect the threat space, while keeping abreast of changes in the nature of future threats. - Assessment of synthetic biological tools and other biotechnology developments that can enhance or alter the threat space. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Complete the Threat Area Panel (TAP) efforts at US Army Medical Research Institute of Infectious Disease (USAMRIID). Complete and augment horizon scanning capabilities, including identification of knowledge gaps for emerging/future agents enhancing or altering the biological threat space, and use these to inform more focused studies within Threat Agent Science. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project is entering completion and all activities will be closed.</p> | | | |
| <p>Title: 21) Distributed Biological Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate. Early indications from capabilities under CB Reconnaissance will allow for enhanced warning of threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to develop innovative sensor solutions to increase situational threat awareness and provide operational advantage. - Continue to develop low-cost, low Size, Weight and Power (SWaP), and low-burden, with little to no dependence on supply chain, detection technologies to support of tactical and dismounted site assessment missions. | - | 1.598 | 1.741 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>- Continue to enhance sensing capabilities for unmanned vehicles and its integration into mobile platforms.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue to develop innovative sensor solutions and make technological improvements to include early warning of aerosolized biological threats. -Continue to explore fundamental science and novel technologies to increase sensing performance through enhanced speed and specificity; low size, weight, and power (SWaP); low-burden; and reduced consumables and life-cycle costs of fielded biological sensors. - Continue developing enhanced sensing capabilities and sampling systems, to include unmanned vehicles and mobile platforms. - Initiate the use of computational tools, like machine learning, into detector/identifier technologies to further reduce false reporting due to environmental factors. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | |
| <p>Title: 22) Emerging and Enhanced Biothreat Sensing</p> <p>Description: Establish robust capability to assess emerging and enhanced biological threats to rapidly develop biosensors for detecting emerging or enhanced biological threats. Quickly develop adaptable, analyte-agnostic laboratory and field-forward detection capabilities to provide a spectrum of improved detection assets for novel threats. This thrust area leverages multi-omics data science or the combining multiple measurements to inform rational and rapid design and development of biodetection solutions. Synthetic biological concepts will be thoroughly evaluated and exploited for the development of biosensing solutions and refinement of laboratory methods.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection and identification capabilities that discern if pathogens are genetically manipulated and/or identify pathogens of unknown origin. - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Transition far-forward pathogen agnostic sensing toolkit to provide on-site threat identification while reducing the burden on the Warfighter by using technologies that rely on little to no supply chain disposables. - Continue development of on-demand biological threat detection assays that provide the Warfighter with the ability to rapidly respond to emerging biological threats and provide only the assay needed for threat identification and therefore reducing cost and reagents needed by most current assay kits. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection and identification capabilities that discern if pathogens are genetically manipulated and/or identify pathogens of unknown origin. | - | 2.069 | 3.453 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <ul style="list-style-type: none"> - Continue development of detection algorithms, laboratory workflows, and implementation of bioinformatics analysis tools to identify threats in unknown samples - Continue development of assays on demand biological threat detection assays that provide the Warfighter with the ability to rapidly respond to emerging biological threats and provide only the assay needed for threat identification and therefore reducing cost and reagents needed by most current assay kits. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | | |
| <p>Title: 23) Unattended Perimeter Monitoring - Biological Detection</p> <p>Description: Establish a layered defense capability by developing and implementing automated and integrated technologies enabling unattended monitoring for chemical and biological threats. These technologies will provide early warning of vapor, aerosol, solid, and liquid hazards and unencumber the Warfighter by reducing logistics and operator burden. Providing a reliable detect-to-warn capability at fixed or expeditionary sites will enhance the overall protective posture of ground and maneuver forces as robust technologies can be miniaturized for portability and operational sustainment.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Transition automated biological collection, detection and identification system. Fully autonomous system will reduce errors by eliminating the need for laboratory personal to perform analysis. - Initiate efforts to modernize capabilities to reduce false alarms and increase sensitivity and specificity. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to modernize capabilities to reduce false alarms and increase sensitivity and specificity. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | - | 1.177 | 1.283 |
| <p>Title: 24) Unconventional Biological Detection Modalities</p> <p>Description: Develop disruptive technologies to identify unknown or emerging biological threats and develop biological sensors that can operate in complex threat environments with high fidelity. This effort supports the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete development and refinement of integrated photonics. - Complete development and refinement of miniaturized Raman spectrometers. - Complete development and refinement of machine learning algorithms for integrating disparate sensor feeds. | | - | 0.871 | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) UN3 / <i>Understand (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| - Initiate library-less detection efforts to move towards threat agnostic detection and provide rapid-fielded capabilities to address emerging biological threats. - Continue development of state of the art size and speed of detection technologies that include advances in computational tools, Artificial Intelligence (AI)/Machine Learning (ML) to address the most difficult changes in biological detection. <i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> Decrease due to change in program/project schedule. | | | |
| Accomplishments/Planned Programs Subtotals | - | 68.415 | 83.825 |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| Line Item | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| • UN4: <i>Understand (ACD&P)</i> | - | 52.708 | 61.638 | - | 61.638 | 64.399 | 48.874 | 41.264 | 38.169 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|----------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| PT3: <i>Protect (ATD)</i> | - | 0.000 | 32.113 | 29.261 | 0.000 | 29.261 | 48.969 | 42.794 | 46.159 | 52.581 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

The Protect Advanced Technology Development (ATD) Project enhances mission performance while providing effective protection against current and emerging chemical and biological (CB) threats, enables Joint Force lethality by protecting Warfighters against adverse effects of CB hazards, and fields protection capabilities against engineered biological agents, opioids and other Pharmaceutical Based Agents (PBAs), and Fourth Generation Agents (FGAs). In FY 2023, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. PT3 efforts in FY 2022 remain in Projects CB3 and TM3. This restructuring provided standardization and alignment across CBDP research, development and acquisition efforts.

Thrust Areas included in this Project are:

- (1) Biological Warfare Defense Prophylaxis
- (2) Air Purification Enhancements
- (3) All-Hazards & Respiratory Protection
- (4) Dynamic Multifunctional Materials for Second Skin
- (5) Enhanced Survivability Coatings
- (6) Lightweight Protective Garments
- (7) Multifunctional Materials for Protection
- (8) Nerve Agent Prophylaxis/Pretreatments

Biological Warfare Defense Prophylaxis: Provides the Warfighter protection against biothreat agents through the pre-exposure administration of prophylactics against known bacterial, viral and toxin agents of interest and emerging infectious threats. Medical countermeasure (MCM) strategies against broader classes of biological agents will be pursued with emphasis on broad-spectrum protection based on mechanism of action. The manufacturing and formulation processes for platform technologies will be adapted to maximize flexibility, increase stability, shelf life, and expand storage conditions. Efforts will also be adapted to maximize delivery flexibility through modifying delivery routes, which will allow for dose and reagent sparing.

Air Purification Enhancements: Optimizes and extends filter life and reduces lifecycle costs while maintaining or enhancing protection against all chemical weapons agents and toxic industrial chemicals/materials. Improves integration of collective protection into developmental Service major combat platforms. Investigates existing filtration performance against emerging and non-traditional threats and identify and develop countermeasures. Efforts include additional investments in enhanced biodefense and pandemic preparedness.

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | Date: March 2023 |
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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> |
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All Hazards and Respiratory Protection: Develops next generation general purpose mask that unencumbers the warfighter, integrates with existing system technology, and closes capability gaps in current technologies. Supports special purpose units (e.g., special operations, Civil Support Teams, Explosive Ordnance Disposal) and modernization efforts to insert new, scalable protection technologies into current respirator programs of record that protect against the full spectrum of threats for the full range of military operations. Develops next generation antimicrobial respiratory protection. Efforts include additional investments in enhanced biodefense and pandemic preparedness.

Dynamic Multifunction Materials for Second Skin: Efforts support percutaneous protection and will utilize responsive technologies to provide chemical and biological protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments. These technologies include interpenetrating polymer networks that will change moisture permeability and molecular selectivity on demand, and membranes with higher moisture vapor transfer rates than existing fabrics.

Enhanced Survivability Coatings: Addresses materiel surface ease of decontamination and resistance to chemical agent penetration. Develops durable temporary coatings that resist chemical agent absorption and are quickly decontaminated in the field and allow the rapid regeneration of combat power.

Lightweight Protective Garments: Advances garment material and ensemble technologies with revolutionary capability improvements using integrated, low encumbrance garment designs and fabrication for thermal burden reduction. Incorporates state-of-the-art threat protection technologies and supporting test methodologies and methods that provide operationally relevant, comparable test data on garments. Improves testing methods for rapid, operationally-relevant, consistent garment performance evaluation. Develops next generation antimicrobial percutaneous protection to extend protective garment service life and reduce logistics and lifecycle costs. Efforts include additional investments in enhanced biodefense and pandemic preparedness.

Multifunctional Materials for Protection: Supports Protection and Hazard Mitigation Core Capability Areas. Combines basic and applied research to discover, develop, engineer, and integrate novel, reactive/catalytic materials into next generation CB defense systems. Engineers and scales material manufacturing to maximize sorption, reactivity, and service life while unencumbering the warfighter. Characterizes materials using state-of-the-art ambient pressure spectroscopies for integration into next generation filters and protective garments that reactively decontaminate chemical warfare agents.

Nerve Agent Prophylaxis/Pretreatments: Obtain the first prophylactic MCMs designed to prevent severe morbidity and mortality upon exposure to nerve agents without the need for additional individual physical protective equipment.

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

| | FY 2022 | FY 2023 | FY 2024 |
|--|---------|---------|---------|
| <p>Title: 1) Biological Warfare Defense Prophylaxis</p> <p>Description: The ultimate protection of the Warfighter is by pretreating the Warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the Warfighter to work in a less restrictive environment, absent of any personal protective equipment allowing operation at peak performance. Investments support de-risking of candidates for transition into advanced development and includes: platform and prototype candidate maturation, pre-clinical studies for lead candidates to allow initiation of clinical work, regulatory science to support clinical initiation, animal model</p> | - | 24.826 | 15.082 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>development for Food and Drug Administration (FDA) animal rule licensure, and Phase 1 clinical trials. Candidates transition into advanced development once the Phase 1 clinical trial is complete.</p> <p>FY 2023 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Complete Good Manufacturing Practices (GMP) manufacturing for Tularemia prophylaxis with the ClpB vaccine and Burkholderia Capsular Polysaccharide-bacterial virulence factor (CPS) conjugate vaccine for advancement to clinical Phase 1. - Complete manufacturing and nonclinical development of adjuvanted plague vaccine for advancement to clinical Phase 1. - Initiate toxicology studies of adjuvanted plague vaccine in support of clinical Phase 1. - Continue non-clinical safety and efficacy studies of monoclonal antibody cocktail against plague and Burkholderia. - Continue layered defense studies for bacterial threats to test vaccines, antibody therapies and antibiotics in combination. - Continue non-clinical safety and efficacy studies on a live attenuated plague vaccine candidate for advancement to clinical Phase 1. - Initiate manufacturing of anthrax CPS conjugate vaccine candidate for advancement to clinical Phase 1. - Complete melioidosis human seroprevalence study in support of vaccine licensure. - Complete assay development in support of clinical Phase 1 for complex vaccines. <p>Viral:</p> <ul style="list-style-type: none"> - Complete current Good Manufacturing Practices (cGMP) manufacture of deoxyribonucleic acid (DNA) Vaccine for the upcoming Phase 1 clinical trial as well as pivotal nonclinical studies. - Continue cGMP manufacture of recombinant vesicular stomatitis Virus (rVSV) Marburg virus vaccine to support pivotal animal studies and upcoming Phase 1 clinical trial. - Complete investigation into correlates of protection for Marburg virus survivors to support pivotal animal studies. - Continue correlates of protection studies for alphavirus vaccine animal models. - Continue evaluation and mitigation studies of Filovirus aerosol pathology. - Continue development of rVSV Marburg vaccine in animal models to support investigational new drug (IND) submission. - Complete Investigational New Drug (IND) package for DNA vaccine for Venezuelan Equine Encephalitis (VEE) Virus for upcoming Phase 1 clinical trial. - Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines - Continue assay qualification and validation for Marburg virus, and alphavirus vaccines. <p>Broad Spectrum:</p> <ul style="list-style-type: none"> - Continue development of the multivalent Nanolipoprotein (NLP) vaccine against multiple bacterial agents. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue non-clinical safety and efficacy studies with the broad spectrum NLP vaccine for advancement to clinical Phase 1.</p> <p>FY 2024 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Initiate Phase 1 vaccine clinical trial in collaboration with Australia for the Burkholderia OMV vaccine. - Continue building relationships in Madagascar to collect plague survivor samples for identification of vaccine antigen targets from emerging plague strains <p>Viral:</p> <ul style="list-style-type: none"> - Initiate Phase 1 clinical trial for the VEE deoxyribonucleic acid (DNA) Vaccine. - Continue preclinical development of Hydrovax pan-Alphavirus vaccine - Continue preclinical development of mucosal SARS CoV2 vaccine, expanding to multivalent coronavirus vaccine - Complete Current Good Manufacturing Practices (cGMP) manufacture of Recombinant Vesicular Stomatitis Virus rVSV Marburg virus vaccine and IND enabling studies to support pivotal animal studies and upcoming Phase 1 clinical trial. - Continue correlates of protection studies for viral vaccines. - Continue evaluation and mitigation studies of Filovirus aerosol pathology. - Continue development of rVSV Marburg vaccine in animal models to support investigational new drug (IND) submission. - Continued development of alphavirus animal models to support animal rule licensure of alphavirus vaccines - Continue assay qualification and validation for Marburg virus, and alphavirus vaccines <p>Broad Spectrum:</p> <ul style="list-style-type: none"> - Continue layered defense studies for pathogen threats to test vaccines, antibody therapies and antibiotics in combination to broaden protection. - Continue development of the multivalent Nanolipoprotein vaccine against multiple bacterial agents. - Continue preclinical development of universal cellular nanosponge MCM to protect against multiple respiratory viruses. - Continue non-clinical safety and efficacy studies with the broad spectrum NLP vaccine for advancement to clinical Phase 1. - Initiate development of oral multivalent mRNA vaccine <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to change in program/project technical parameters. All work associated with plague vaccines has been canceled</p> | | | | |
| <p>Title: 2) Air Purification Enhancements</p> <p>Description: Existing Collective Protection (ColPro) systems have high life cycle costs driven by maintenance and limited service life. Efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.</p> | | - | - | 0.117 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 |
| <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Transition improved, compact vehicle ColPro system filters to the Modernization ColPro program of record to broaden the spectrum of threat protection and reduce production and replacement costs. - Transition the Residual Life Indicator System to the Modernization ColPro program of record to accurately predict remaining filter life, reducing cost and logistics for facility and shipboard ColPro systems. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred from another funding line. Project funding transferred from the Multifunctional Materials for Protection thrust area to support transition of Residual Life Indicator System to the Modernization ColPro program of record. Increase supports follow-up testing for transitioned technologies.</p> | | | |
| <p>Title: 3) All-Hazards & Respiratory Protection</p> <p>Description: Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new manufacturing techniques and materials; perform early surveys for end-user jury input with frequent user operational evaluation; focus on low burden next generation protective mask.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to evaluate and assess systems that provide CB respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Transition operationally-relevant respirator fit testing system to Modernization Individual Protection program of record. - Transition specification for anti-fog lenses in respirators as a Ground Mask modification work order. - Continue to design and test prototypes for a low-encumbrance, next generation protective mask. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Transition a microcooling-garment system that extended the time for mission operations to the Tactical Advanced Threat Protective Ensemble (TATPE) effort under the UIPE FoS GP program of record. - Complete design challenge for next generation respiratory protection concepts. - Perform early user assessment of next generation prototype respiratory protection concepts in the form of a low-burden, unencumbering respirator that integrates with existing systems (e.g., helmets and displays) and may include off-the-face and low profile filter designs. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | - | 1.345 |
| <p>Title: 4) Dynamic Multifunction Materials for Second Skin</p> | | - | 1.170 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>Description: This effort utilizes responsive technologies to provide CB protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development and testing of protective garment materials that respond to the presence of chemical agents to increase Warfighter protection. - Begin integration of responsive systems into protective suit paradigms for whole system testing. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred to another funding line. Dynamic Multifunctional Materials for Second Skin thrust area ends in FY23 and merges into the Lightweight Protection Garments, Enhanced Survivability Coatings, and Multifunctional Materials for Protection thrust areas starting in FY24.</p> | | | |
| <p>Title: 5) Enhanced Survivability Coatings</p> <p>Description: Efforts seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminatability of military materiel to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return materiel to unprotected mission operations level.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to characterize bio-inspired surface treatments for materiel coatings to repel agents of interest from materiel surfaces. - Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays. - Advance thin repellent film coating systems from fundamental research to applied research test and evaluation. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Transition candidate temporary overcoats that are commercially-available, improve success of decontamination, have low impact on signature, and reduce logistics to the TTC (Tactical Temporary Coatings) program of record. - Continue to evaluate and demonstrate industry polymer coatings as potential temporary or permanent military equipment coatings to decrease logistical burden of decontamination in support of the TTC program of record. - Conduct operational user assessments to validate temporary overcoats that improve decontamination for equipment elastomers. <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> | - | 0.416 | 0.629 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| Program/project funding transferred from another funding line. Project funding transferred from the Dynamic Multifunctional Materials for Second Skin thrust area which ends in FY23. Increase supports transition of candidate temporary overcoats to the TTC program of record in FY24. | | | | |
| <p>Title: 6) Lightweight Protective Garments</p> <p>Description: Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Manufacture scaled responsive/reactive prototype garments that adapt or react to the threat and environment while reducing thermal burden and integrate with current combat garments. - Test scaled responsive/reactive prototype garments using whole system test methods. <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> <p>Program/project funding transferred from another funding line. Project funding transferred from Dynamic Multifunctional Materials for Second Skin thrust area which ended in FY23. Increase supports whole system chemical permeation testing of textile swatches.</p> | | - | - | 0.117 |
| <p>Title: 7) Multifunctional Materials for Protection</p> <p>Description: Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity. They will characterize materials using state-of-the-art in operando and ambient pressure spectroscopies for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials (derived from Applied Research efforts) into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Advance next generation materials to design reactive, regenerative protective garments with longer service life and lower thermal burden. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Generate prototype next generation reactive and regenerative protective garment prototypes with longer service life and lower thermal burden for whole system testing. | | - | 0.756 | 1.404 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Integrate responsive technologies to develop prototype protective suits that adapt to the environment by switching between low burden and high protection mode on demand in response to the presence of CB agents, offering proactive contamination protection.</p> <p>- Integrate reactive materials into filters for enhanced threat spectrum protection, extending service life and regenerative capacity.</p> <p>- Scale materials manufacturing processes for cost-efficiency.</p> <p>- Characterize materials using operationally-relevant test methods and conditions.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred from another funding line. Project funding transferred from the Dynamic Multifunctional Materials for Second Skin thrust area which ends in FY23. Increase supports development of prototype regenerative protective garments.</p> | | | | |
| <p>Title: 8) Air Purification Enhancements - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Improved Collective Protection (ColPro). Existing ColPro systems have high life cycle costs driven by maintenance and limited service life. Efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop low cost, continuous-operation collective protection engineering standards and guidelines for temporary, rapid enhancement of unprotected Department of Defense (DoD) facilities during pandemic or biological warfare agent release. - Demonstrate and validate concepts for layered protection to mitigate the biological contamination risk with passive systems for applique and facility design features. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Generate validated experimental data that quantifies the range of biological infection risk reduction based on indoor air quality measurements. - Use appropriate, validated experimental methodologies to characterize and compare the impact of collective protection biological infection risk and cost, and plan operationally-relevant testing. | | - | 2.000 | 2.000 |
| <p>Title: 9) All-Hazards & Respiratory Protection - Enhanced Biodefense (ENBD)</p> <p>Description: Efforts will improve biological agent respiratory and ocular protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new manufacturing techniques and materials; perform early surveys for end-user jury input with frequent user operational evaluation; focus on low burden next generation protective mask specifically for protection against biological agents.</p> <p>FY 2023 Plans:</p> | | - | 1.000 | 1.500 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Develop low cost, low burden, antimicrobial respiratory and ocular for operations specifically in a biologically contaminated environment.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Identify potential antimicrobial textiles and innovative designs for respirators by partnering with industry, Department of Defense laboratories, and academic performers. - Evaluate textiles for bactericidal and bacteriostatic effects using standardized test methods. - Scale manufacturing of candidate antimicrobial textiles for respirator prototypes. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred from another funding line. Funding transferred from Lightweight Protective Garments. Increase supports development and testing of antimicrobial respirator in FY24.</p> | | | | |
| <p>Title: 10) Lightweight Protective Garments - Enhanced Biodefense (ENBD)</p> <p>Description: Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data specifically for test garments that protect against biological threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop low cost, low burden, antimicrobial respiratory and ocular for operations specifically in a biologically contaminated environment. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Partner with industry, Department of Defense laboratories, and academic partners to identify potential antimicrobial textiles for evaluation. - Down select and evaluate textiles for bactericidal and bacteriostatic effects using standardized test methods. - Scale manufacturing of candidate antimicrobial textiles for prototype garments. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred to another funding line. Funding transferred to All Hazards Respiratory Protection.</p> | | - | 0.600 | 0.500 |
| <p>Title: 11) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter chemical warfare agents, including organophosphorus nerve agents (OPNA), using targeted and innovative science and technology efforts that will offer broad-spectrum protection, flexible route of administration, lower dose requirements, and reduced operational and logistical burden. The use of these medical</p> | | - | - | 6.000 |

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) PT3 / <i>Protect (ATD)</i> |
|--|--|--|

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|--|---------|---------|---------|
| countermeasures (MCM) will protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability. | | | |
| <i>FY 2024 Plans:</i> - Continue to advance candidate bioconjugated organophosphorus hydrolase (OPH) mutants as catalytic nerve agent prophylaxes through current Good Manufacturing Practice (cGMP) production and on-Good Laboratory Practice (GLP)/GLP efficacy, toxicity and PK studies. | | | |
| <i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> Program/project funding transferred from another funding line. FY 2024 funding has been transferred from MT4 to Project MT3 for better alignment under budget activity 3. | | | |
| Accomplishments/Planned Programs Subtotals | - | 32.113 | 29.261 |

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

| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|-----------------------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • PT4: <i>Protect (ACD&P)</i> | - | 175.219 | 179.158 | - | 179.158 | 135.096 | 107.341 | 123.538 | 139.376 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
|--|--|---|
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) MT3 / <i>Mitigate (ATD)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|----------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| MT3: <i>Mitigate (ATD)</i> | - | 0.000 | 86.157 | 100.791 | 0.000 | 100.791 | 89.511 | 91.704 | 85.795 | 85.480 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

The Mitigate Advanced Technology Development (ATD) Project provides the Joint Force the ability to preserve combat power by mitigating exposure to chemical and biological (CB) hazards and restoring combat readiness of critical personnel and platforms. In FY 2023, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. MT3 efforts in FY 2022 remain in Projects CB3 and TM3. This restructuring provided standardization and alignment across CBDP research, development and acquisition efforts.

Thrust Areas included in this Project are:

- (1) Biological Warfare Defense Therapeutics
- (2) Discovery of Medical Countermeasures Against New and Emerging (DOMANE)
- (3) Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD)
- (4) Emerging and Pharmaceutical-based Agent Threats (EMPATH)
- (5) Reactivators of Acetylcholinesterase as Therapeutics (ReACT)
- (6) Enhanced Survivability Coatings
- (7) Equipment Decontamination
- (8) Multifunctional Materials for Protection
- (9) Personnel Decontamination
- (10) Wide Area Decontamination

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

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

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Chemically Reactive Ocular Wound and Dermal Therapeutics (CROWD): Develop a fielded medical countermeasure for the Warfighter that can treat a chemical agent that has breached the skin. Collect the data that the Food and Drug Administration (FDA) will require for approval.

Emerging and Pharmaceutical-based Agent Threats (EMPATH): Assess candidate MCMs (Medical Countermeasures) for development into fieldable drug products. Activities focus on assessing current therapeutic drugs for protection against opioid agents and developing MCMs to treat non-opioid sedatives.

Reactivators of Acetylcholinesterase (AChE) as Therapeutics (ReACT): Develops broad-spectrum, centrally-acting acetylcholinesterase (AChE) reactivators, that increase survival, reduce morbidity, and decrease neurological damage. Two advanced lead candidates are in development.

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

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

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

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

Wide Area Decontamination: Addresses limited capabilities to rapidly restore critical DoD infrastructure (e.g., sea port or air base) and mitigate contamination spread to enable normal, unprotected operations. Efforts seek to improve contamination mitigation logistics/cost reduction, effectiveness, compatibility/safety, and environmental compatibility. Efforts support autonomous critical area biological decontamination systems. Efforts include additional investments in enhanced biodefense and pandemic preparedness.

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

| | FY 2022 | FY 2023 | FY 2024 |
|---|---------|---------|---------|
| Title: 1) Biological Warfare Defense Therapeutics | - | 29.439 | 29.703 |
| FY 2023 Plans: Bacterial: - Continue efforts to identify and advance bacterial therapeutic candidates, with a focus on non-traditional candidates. Therapeutic candidates that are shown to be both safe and efficacious against Biological Warfare (BW) threats will advance | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>for additional nonclinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP) or transition to an advanced developer.</p> <ul style="list-style-type: none"> - Continue to partner with interagency, international and industry partners to fund nonclinical BW therapeutic efficacy studies for therapeutic candidates already in advanced development for public and force health indications. - Continue to execute proof of concept efficacy studies for antibiotic therapy in combination with prophylaxis or complimentary treatments (layered medical defense). Advance layered combinations toward proof of concept in non-human primate (NHP) models. <p>Viral:</p> <ul style="list-style-type: none"> - Continue efforts to identify and advance viral therapeutic candidates against new and existing BW viral threats, including direct acting, broad-spectrum anti-virals and monoclonal antibodies. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP) or transition to an advanced developer. - Continue proof of concept viral therapeutic efficacy studies for combinations of therapeutics including, small molecule, monoclonal antibody and host-directed therapeutics. <p>Toxins:</p> <ul style="list-style-type: none"> - Continue to evaluate efficacy of repurposed drug for treatment of botulinum neurotoxin (BoNT) A intoxication in NHP animal model. <p>FY 2024 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Continue efforts to identify and advance bacterial therapeutic candidates, including non-traditional candidates. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation or transition to other therapeutic efforts or an advanced developer. Two broad-spectrum therapeutic candidates will advance to the Department of Health and Human Services, Biomedical Advanced Research and Development Authority for continued development. - Continue to partner with interagency, international and industry partners to fund nonclinical BW therapeutic efficacy studies for therapeutic candidates already in advanced development for public and force health indications. - Continue to execute proof of concept efficacy studies for antibiotic therapy in combination with prophylaxis or complimentary treatments (layered medical defense). Advance layered combinations toward proof of concept in non-human primate (NHP) models. <p>Viral:</p> | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Continue efforts to identify and advance viral therapeutic candidates against new and existing BW viral threats, including host targeted and direct acting, broad-spectrum anti-virals and monoclonal antibodies. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation or transition to other therapeutic efforts or an advanced developer. One broad-spectrum therapeutic candidate will advance to the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense Antiviral Oral Therapeutic Program for continued development.</p> <p>- Continue proof of concept viral therapeutic efficacy studies for combinations of therapeutics including, small molecule, monoclonal antibody and host-directed therapeutics.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | | |
| <p>Title: 2) Biological Warfare Defense Therapeutics - Enhanced Biodefense (ENBD)</p> <p>Description: This effort focuses on Drug Repurposing; Micro physiological Systems; Small Molecule Libraries; and Science & Technology Host Response Studies. Activities include expediting a response to emerging threats by assessing broad-spectrum efficacy of approved drugs against biological threats (i.e., drug repurposing), advancing repurposed drugs against biological threats for U.S. Food & Drug Administration (FDA) approval; developing tools (e.g., small molecule libraries) to expedite discovery and development of therapeutic candidates in response to an emerging threat; and, identifying and developing technologies that target host response to disease caused by biological threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate and accelerate projects to repurpose broad-spectrum drugs against viral, bacterial and toxin threats. - Initiate and continue projects to create and sustain curated, searchable databases of molecules with toxicity, drug development and efficacy data for use in a response to emerging biological threats. - Initiate development of host-targeted technologies that can be used to stop progression of disease caused by viral threats. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue to repurpose broad-spectrum drugs against viral, bacterial and toxin threats. - Continue to create and sustain curated, searchable databases of molecules with toxicity, drug development and efficacy data for use in a response to emerging biological threats. - Continue to develop host-targeted technologies that can be used to stop progression of disease caused by viral threats. | | - | 23.000 | 23.000 |
| Title: 3) Biological Warfare Defense Therapeutics | | - | - | 3.984 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
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| <p>Description: Funds biomedical research focused on the nonclinical and early clinical development of therapeutic countermeasures against known and emerging viral, bacterial, and toxin biological warfare (BW) threats for which U.S. Food & Drug Administration (FDA) approved therapeutics are limited or lacking. BW defense therapeutics mitigate and reverse the effects of known and emerging viral, bacterial, and toxin biological warfare threats in symptomatic warfighters diagnosed with BW disease. They are the last line of defense against BW threats and are critical to returning symptomatic warfighters to service. Biomedical research is focused on nonclinical development (e.g., animal model, and formulation/manufacturing studies) and early clinical evaluation of broad-spectrum therapeutic candidates that target viruses, bacteria or toxins directly, enhance the host response (e.g., by modulating the immune system) and/or relieve BW disease symptoms. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for further non-clinical and/or clinical evaluation under RDT&E budget activity 5, and can be accelerated for use against emerging infectious diseases during an outbreak. Clinical and nonclinical evaluation of novel small molecules (chemically synthesized), novel biologic molecules (isolated from natural sources), drug and drug/vaccine combinations (aka layered defense), and repurposing of drugs approved by the FDA or in clinical development for other indications, are included in this research. Refinement of appropriate animal models in which to evaluate therapeutic candidates is also included. Projects leverage interagency and commercial sector investments to accelerate development and reduce costs.</p> <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue nonclinical and regulatory activities to transition broad spectrum antibacterial candidate to Biomedical Advanced Research and Development Authority (BARDA). - Initiate clinical and/or nonclinical studies for broad-spectrum antiviral therapeutic candidates. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Program/project funding transferred from another funding line. FY 2024 funding has been transferred from Project PT4 for better alignment under budget activity 3.</p> | | | |
| <p>Title: 4) Discovery of Medical Countermeasures Against New and Emerging (DOMANE)</p> <p>Description: This effort focuses on predicting pathogenesis of pathogens and toxins while using artificial intelligence (AI) and machine learning (ML) to identify targets for both host and pathogen while conducting high throughput screens using new structural models with AI to predict and recommend potential therapeutics. It supports DOMANE thrusts like Pathogenesis and Toxicity forecasting using Multi-Organoid Systems (PATMOS) prototype, which develops an advanced-artificial intelligence (AI) assisted multi-organoid system capable of forecasting pathogenesis of viral threats and toxicity of biotoxin threats. It supports DOMANE thrusts like Medical Countermeasure Finder (MEDFIND) to prototype a flexible advanced AI-assisted system capable of harnessing repurposed drugs and generate effective therapeutic intervention strategies against viral and biotoxin threats.</p> | - | 3.403 | 7.469 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continued development of prototype capability that forecasts pathogenicity or toxicity of biological threats. - Continued development of prototype capability for high-throughput screening to produce high resolution target and MCM identification. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue prototype development of PATMOS platform for high resolution forecasting of pathogenesis that occurs during interaction of new and emerging biological threats and providing initial safety data on recommended medical countermeasures. - Continue development of prototype development of ambient ionization mass spectroscopy high-throughput screens (AIM-HITS) system to rapidly characterize MCMs by collecting and analyzing large amounts of structural data and use AI/ML to recommend new MCMs. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | | |
| <p>Title: 5) Discovery of Medical Countermeasures Against New and Emerging (DOMANE) - Enhanced Biodefense (ENBD)</p> <p>Description: This effort focuses on predicting pathogenesis of pathogens and toxins while using artificial intelligence (AI) and machine learning (ML) to identify targets for both host and pathogen while conducting high throughput screens using new structural models with AI to predict and recommend potential therapeutics. It supports DOMANE thrusts like Pathogenesis and Toxicity forecasting using Multi-Organoid Systems (PATMOS) prototype, which develops an advanced- AI assisted multi-organoid system capable of forecasting pathogenesis of viral threats and toxicity of biotoxin threats. It supports other DOMANE thrusts like Medical Countermeasure Finder (MEDFIND) to prototype a flexible advanced AI-assisted system capable of harnessing repurposed drugs and generate effective therapeutic intervention strategies against viral and biotoxin threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Prototype development PATMOS platform for high resolution forecasting of pathogenesis that occurs during interaction of a biological threat. - Prototype initiation for MEDFIND platform to identify repurposed drugs using AI and Machine Learning (ML). <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue prototype development of PATMOS platform for high resolution forecasting of pathogenesis using organoid platforms that occurs during interaction of new and emerging biological threats. - Initiate 2nd PATMOS prototype to provide additional pathogenesis forecasting capability along with recommending MCMs for treatment. | - | 12.000 | 12.000 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>-Continued prototype development of ambient ionization mass spectroscopy high-throughput screens (AIM-HITS) system to rapidly characterize MCMs and continued development of cryo-electron microscopy (cyro-em) prototype with high throughput system to characterize MCMs at the atomic level combined with AI/ML to recommend MCMS for new and emerging threats.</p> <p>- Continue prototype development for MEDFIND platform to identify repurposed and new drugs using AI and ML using high throughput screens and micro-electron diffraction to deliver crystal structures on the atomic scale to enable accurate target and host characterization leading to designing new MCMs.</p> | | | |
| <p>Title: 6) Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD)</p> <p>Description: Focuses on therapeutic strategies to effectively treat Chemical Warfare Agents (CWA) contamination on wounds, eyes, and large areas of intact skin. This effort involves the development of products capable of removing or neutralizing CWA from those routes of exposure, to decrease the toxic load of agent and allow optimal effectiveness of other systemic therapeutics.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Submit investigational new drug (IND) submission to the FDA for organophosphorus nerve agents (OPNA) catalytic scavenger enzymes. - Complete Good Laboratory Practice (GLP) pharmacokinetics, immunogenicity and efficacy of catalytic scavenger enzyme lead candidates in small animals. - Complete enzyme current Good Manufacturing Practice (cGMP) manufacturing scale-up. - Complete formulation efforts. - Complete enzyme non-cGMP manufacturing scale-up. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Perform advanced preclinical studies to validate safety and efficacy in support of clinical trials. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | - | 1.174 | 2.500 |
| <p>Title: 7) Emerging and Pharmaceutical-based Agent Threats (EMPATH)</p> <p>Description: Focus on therapeutic and proactive strategies to effectively minimize injuries and/or death resulting from exposure to Pharmaceutical Based Agents (PBA). This will allow the warfighter to maintain operational capacity in a chemically contested battlefield scenario. This effort involves the evaluation U.S. Food & Drug Administration (FDA) approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for FDA licensure or to identify previously licensed products for new uses in the treatment and pretreatment against chemical warfare injury.</p> <p>FY 2023 Plans:</p> | - | 1.463 | 4.361 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <ul style="list-style-type: none"> - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. - Assess operational feasibility of employing FDA approved opioid antagonist MCM to provide extended duration of protection. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue cGMP production and non-GLP/GLP safety and/or efficacy assessment of a novel, multi-dose vialled formulation. - IND filing and initiation of a human bioavailability/bioequivalence study to support an New Drug Application (NDA) filing for a novel, multi-dose vialled formulation. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to fact of life change in the program/project.</p> | | | | |
| <p>Title: 8) Reactivators of AChE as Therapeutics (ReACT)</p> <p>Description: The Warfighter requires rapid acting MCMs to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation. Efforts in this area are focused on formulation development and pre-clinical studies for potential candidates that will ultimately be submitted for FDA licensure or previously licensed products for new uses in the treatment of chemical warfare casualties.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to advance pre-clinical development of lead therapeutic candidates. - Continue formulation efforts and scale up manufacturing for lead therapeutic candidates. - Initiate GLP toxicology and long-term stability studies for lead therapeutic candidates. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue to advance pre-clinical development of lead therapeutic candidates. - Complete IND-enabling studies on the current lead reactivator candidates. - Continue development efforts in preparation for IND/phase 1 clinical trials, including cGMP manufacturing. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters. FY 2024 funding has been transferred from Project MT4 for better alignment under budget activity 3.</p> | | - | 3.618 | 8.205 |
| <p>Title: 9) Enhanced Survivability Coatings</p> <p>Description: Efforts seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military materiel to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return materiel to unprotected mission operations level.</p> | | - | 0.051 | 0.074 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p><i>FY 2023 Plans:</i></p> <ul style="list-style-type: none"> - Continue to characterize bio-inspired surface treatments for equipment coatings to repel agents of interest from current military equipment coatings. - Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays. - Advance thin repellent film coating systems from fundamental research to applied research test and evaluation. <p><i>FY 2024 Plans:</i></p> <ul style="list-style-type: none"> - Transition candidate temporary overcoats that are commercially-available, improve success of decontamination, have low impact on signature, and reduce logistics to the Tactical Temporary Coatings (TTC) program of record. - Continue to evaluate and demonstrate industry polymer coatings as potential temporary or permanent military equipment coatings to decrease logistical burden of decontamination. <p><i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> Minor change due to routine program adjustments.</p> | | | |
| <p><i>Title:</i> 10) Equipment Decontamination</p> <p><i>Description:</i> This effort seeks to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p><i>FY 2023 Plans:</i></p> <ul style="list-style-type: none"> - Transition methodology for testing for effective decontamination of complex surfaces and real-world systems to the Service Equipment Decontamination Systems (SEDS) or Tactical Contamination Mitigation Systems (TCMS) programs of record. - Finish development and demonstration of an autonomous decontamination platform to reduce troop-to-task burden of operational decontamination. <p><i>FY 2024 Plans:</i></p> <ul style="list-style-type: none"> - Demonstrate autonomous equipment decontamination platform to reduce troop-to-task and logistics requirements for operational decontamination. - Transition methodology for decontaminating chemically-contaminated sensitive equipment using hot, humid air. | - | 0.951 | 0.454 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| - Transition methodology for decontaminating bacterial spore-contaminated aircraft using hot, humid air. | | | | |
| <p>FY 2023 to FY 2024 Increase/Decrease Statement: Decrease due to transition of hot air decontamination technologies to Joint Biological Aircraft Decontamination System and Service Equipment Decontamination Systems programs of record in early FY24.</p> | | | | |
| <p>Title: 11) Multifunctional Materials for Protection</p> <p>Description: This effort will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants and coatings.</p> <p>FY 2023 Plans: - Develop and characterize novel reactive/catalytic materials that decontaminate chemical and biological (CB) threats and integrate materials into next generation decontaminants and coatings.</p> <p>FY 2024 Plans: - Integrate reactive materials into decontamination systems for enhanced threat spectrum mitigation. - Continue ambient pressure characterization of reactive chemical decontamination mechanisms. - Scale materials manufacturing processes for cost-efficiency and characterize materials using operationally-relevant conditions.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | - | 0.189 | 0.117 |
| <p>Title: 12) Personnel Decontamination</p> <p>Description: This effort develops decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease warfighter burden in the event of a chemical warfare agent (CWA) exposure by identifying S&T gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2023 Plans: - Develop and use laboratory and animal models to assess physical removal technologies for potential replacement of Reactive Skin Decontamination Lotion (RSDL). - Continue to integrate new dry decontamination into a mitt form factor and determine S&T challenges within process and procedure improvements. This includes investigation of Food and Drug Administration (FDA) requirements for approval of technology as a medical device.</p> <p>FY 2024 Plans:</p> | | - | 0.869 | 2.339 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <p>- Prepare a medical device package for FDA consideration for a new personnel decontamination form factor that reduces sustainment risk of Reactive Skin Decontamination Lotion cold storage and shelf-life concerns for the next generation Medical Decontamination Personnel Skin program of record.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to accelerated development effort.</p> | | | | |
| <p>Title: 13) Wide Area Decontamination</p> <p>Description: Develop processes and identify chemicals to decontaminate critical DoD infrastructure (e.g., sea port or air base) and mitigate contamination spread to enable normal, unprotected operations. Examine commercial bulk packaged chemicals as potential wide area decontaminants and barriers to improve chemical wide area decontamination and improve logistics (i.e., effectiveness in mitigating contamination; compatibility/safety, environmentally friendly; cost reduction).</p> <p>FY 2024 Plans: -Optimize chemical wide area decontamination methods and processes for using commercially-available packaged chemicals for decontaminating critical infrastructure area surfaces for effectiveness, availability, and sprayability/scalability. -Demonstrate chemical wide area decontamination methods, processes, and feasibility for using commercially-available packaged chemicals using operationally-relevant environments and simulants in support of autonomous decontamination.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Funding transferred from Equipment Decontamination thrust.</p> | | - | - | 0.585 |
| <p>Title: 14) Equipment Decontamination - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Improved Decontamination and Disinfectant Options. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements.</p> <p>FY 2023 Plans: - Develop and demonstrate biological disinfection guidelines, procedures, and Concepts of Operations (CONOPs) for Department of Defense (DoD) facility and large-platform interiors, including development of directed energy disinfection methods including plasma and ultraviolet germicidal irradiation.</p> | | - | 5.000 | 5.000 |

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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) MT3 / <i>Mitigate (ATD)</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 |
| <ul style="list-style-type: none"> - Complete comparative laboratory study of Biosafety Level (BSL)-1 surrogate and BSL-2 human coronavirus ultraviolet (UV) disinfection to support field demonstrations. - Develop biological agent disclosure sprays for sensitive, specific biological contamination mapping on surfaces to guide and reduce logistics of decontamination. Explore solution concepts through research, development, and demonstration of one or more functional prototype technologies in a phased approach for a biological agent disclosure spray. - Demonstrate a proof of concept demonstrating specific recognition and binding of the targeted biological warfare agent of interest. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Complete and transition methods for field testing of surface decontamination methods for viruses using a safe, non-infectious surrogate to the Joint Biological Aircraft Decontamination Systems program of record. - Continue development of biological disinfection guidelines, procedures, and CONOPs, for DoD facility and large-platform interiors, including directed energy decontamination approaches. - Optimize and verify laboratory methods for biological agent disclosure sprays for sensitive, specific biological contamination mapping on surfaces to guide and reduce logistics of decontamination. | | | |
| <p>Title: 15) Wide Area Decontamination - Enhanced Biodefense (ENBD)</p> <p>Description: This effort focuses on developing an autonomous decontamination platform to decontaminate critical DoD infrastructure (e.g., sea port or air base) and mitigate biological contamination spread to enable normal, unprotected operations. Examines commercial packaged chemicals as potential wide area decontaminants and barriers to improve biological wide area decontamination and improve logistics (i.e., effectiveness in mitigating contamination; compatibility/safety, environmentally friendly; cost reduction).</p> <p>FY 2024 Plans: Develop concept platform and required subsystems for autonomous wide area biological decontamination, methods, processes, and feasibility and identify and optimize biological decontaminant formulations.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Funding transferred from Equipment Decontamination - Enhanced Biodefense thrust area. Increase supports biological autonomous wide area decontamination project in FY24.</p> | | - | - |
| Accomplishments/Planned Programs Subtotals | | - | 81.157 |
| | | FY 2022 | FY 2023 |
| Congressional Add: Broad Spectrum Small Molecule Anti-viral Development | | - | 5.000 |

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) MT3 / <i>Mitigate (ATD)</i> |
|--|--|---|

| | | |
|---|----------------|----------------|
| | FY 2022 | FY 2023 |
| FY 2023 Plans: Viral: - Enhance viral therapeutic development pipeline by initiating one to two new efforts to identify and advance broad-spectrum viral therapeutic candidates against new and existing biological warfare (BW) viral threats. Therapeutic candidates that are shown to be both safe and efficacious against BW threats will advance for additional nonclinical and clinical evaluation under Advanced Component Development and Prototypes (PE 0603884BP) or transition to an advanced developer. | | |
| Congressional Adds Subtotals | - | 5.000 |

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

| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|------------------------------------|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • MT4: <i>Mitigate (ACD&P)</i> | - | 17.302 | 28.785 | - | 28.785 | 20.885 | 15.433 | 13.369 | - | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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| | | | | | | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|-------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | | | | | | | | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | | | | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| EN3: <i>Enabling Investments (ATD)</i> | - | 0.000 | 39.540 | 43.196 | 0.000 | 43.196 | 43.198 | 44.449 | 44.449 | 44.449 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

The Enabling Investments Advanced Technology Development (ATD) Project focuses on early and continued involvement of the Warfighter in the technology development process and has implemented a user community engagement process to align science and technology (S&T) activities with operational needs and ensure functional design. This process begins with the identification of an innovative technology concept, continues through the assessment of the prototype, and ends at the operational and utility demonstrations to enhance transition to an advanced developer. Enabling efforts in this area support dedicated infrastructure capabilities, demonstrations, and overarching development support functions as portfolio enablers responding to emerging threats. In FY 2023, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. EN3 efforts in FY 2022 remain in Projects TM3 and TT3. This restructuring provided standardization and alignment across CBDP research, development and acquisition efforts.

Thrust Areas included in this Project are:

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

Battlefield Readiness: Provides innovative capabilities to the warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provides diagnosis at lower roles of care. Develops field forward medical diagnostics to provide multiplexed detection of biological and toxin threats and leverages immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. Efforts include additional investments in Chem Bio Incident Preparedness and Response.

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

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | Date: March 2023 |
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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> |
|--|--|---|

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

Medical Countermeasures Initiative: Advances medical capabilities to support CB Incident Preparedness and Response (CBIPR). Efforts focus on vaccine platform capability development; novel encapsulation and delivery strategies that optimally tune the immune response to provide greater protection from a vaccine as well as laboratory sustainment for the Animal Model/Response Capability; genomics; and other medical countermeasure development through antimicrobial susceptibility projects.

ATD: Execution of the ATD campaign plan across the Future Years Defense Program (FYDP) will close the identified gaps by conducting dynamic mission-oriented, scenario based, threat relevant integrated capability demonstrations with Warfighters employing innovative, mature and optimized S&T technologies.

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

User Assessment: Execution of the User Assessments provide dynamic mission-based scenarios, exercises and field experiments to close identified gaps and can expedite technology development as well as ensure transition and fielding success.

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| <p>Title: 1) Battlefield Readiness</p> <p>Description: Provide innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care. Develop field forward medical diagnostics that allow for multiplexed detection of biological and toxin threats. Leverage immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. These funds support CB Incidence Preparedness Response (CBIPR).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue the development of additional panels for infectious disease diagnostic tests on the immunological diagnostic platform. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue the development of additional panels for infectious disease diagnostic tests on the immunological diagnostic platform. <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> | - | 5.094 | 4.658 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| Minor change due to routine program adjustments. | | | | |
| <p>Title: 2) Diagnostic Building Blocks</p> <p>Description: Lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. These funds support CB Incidence Preparedness Response (CBIPR).</p> <p>FY 2023 Plans: - Continue novel efforts in Artificial Intelligence (AI) and ML for designing assays with high specificity against a broader range of CB agents to enable an agile response to emerging threats.</p> <p>FY 2024 Plans: - Continue novel efforts utilizing AI and ML for designing assays with high specificity against a broader range of chemical and biological agents to enable an agile response to emerging threats.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | - | 3.962 | 4.075 |
| <p>Title: 3) Emerging Threats</p> <p>Description: Advance the diagnosis of emerging and/or low prevalence but high threat biological agents leveraging novel technologies. Develop threat agnostic tests based on host biomarkers that identify known or emerging bacterial or viral infections. Characterize markers for antibiotic resistance or susceptibility to identify challenging threats and inform treatment decisions. Improve capabilities to identify diverse biological agents that are not well characterized using molecular or immunodiagnostic approaches. These funds support CB Incidence Preparedness Response (CBIPR).</p> <p>FY 2023 Plans: - Initiate efforts that establish multiple capabilities for Warfighters to combat new and emerging threats to include identifying novel platforms that are capable of identifying broad classes of threat agents in complex matrices.</p> <p>FY 2024 Plans: - Continue efforts that establish multiple capabilities for Warfighters to combat new and emerging threats to include identifying novel platforms that are capable of identifying broad classes of threat agents in complex matrices.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to change in program/project technical parameters.</p> | | - | 2.264 | 2.912 |
| <p>Title: 4) Medical Countermeasures Initiative</p> | | - | 19.928 | 22.261 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| <p>Description: The Chem Bio Incident Preparedness and Response-Medical Countermeasures Initiative (CBIPR-MCMI) will integrate advances in regulatory science, formulation and delivery technologies and processes. Also will develop animal models, drug discovery and evaluation of platforms as enablers of the advanced development of CBDP medical countermeasure products. These initiatives will lead to the establishment of multi-use platforms, novel formulations and animal models that can be leveraged during a CBRN response to accelerate medical product development and/or regulatory approval as well as reduce overall development costs.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete preclinical studies for Marburg vesicular stomatitis vaccine (VSV) for initiation into a Phase 1 clinical trial. - Continue Burkholderia outer membrane vesicle (OMV) vaccine manufacturing to support Phase 1 clinical trial. - Conduct good laboratory practice (GLP) toxicology on Burkholderia OMV vaccine prior to entry into Phase 1 clinical trial. - Initiate good manufacturing practice (GMP) manufacturing of Francisella tularensis (FnIglD) vaccine to support Phase 1 clinical trial. - Prepare for surprise by establishing drug discovery and evaluation platform capability that can be leveraged during a CBRN response. - Continue to develop and advance animal models to accelerate medical countermeasure (MCM) delivery and the capacity to respond to emerging biological threats. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Conduct evaluation of immune modulation strategies as stand alone, in layered defense and in formulation with vaccines. - Conduct test and evaluation of encapsulation technologies for vaccines that can co-deliver multiple antigens and adjuvants to specific host tissues and tune the immune response resulting in enhanced antigen efficacy and immediate protection with a single dose. - Conduct test and evaluation of mucosal delivery methods for delivery for vaccines that can fine-tune the immune response to vaccines with the goal being vaccines with neutralizing efficacy against a respiratory exposure to an emerging pathogen. Mucosal delivery has the ability to access unique compartments of immunity through intranasal or oral delivery and target that immunity specifically to the site of infection of a respiratory pathogen. - Prepare for surprise by continuing to establish drug discovery and evaluation platform capability that can be leveraged during a CBRN response. - Continue to develop and advance animal models to accelerate medical countermeasure (MCM) delivery and the capacity to respond to emerging biological threats. <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| Increase due to change in program/project schedule. | | | |
| <p>Title: 5) Advanced Technology Demonstration</p> <p>Description: Advanced Technology Demonstrations (ATDs) are Joint Task Force (JTF) scenario-based experiments prioritized on warfighter operational needs that demonstrate and evaluate groupings of integrated technologies or prototype systems. Building on the Technology Concepts and User Assessments thrust areas conducted earlier in the technology maturation process, feedback from the Warfighters during ATDs ensures that these technologies are operationally relevant, value added, and can be matured and potentially transitioned in a timely and effective manner to transition partners for advanced development and employment across the spectrum of Joint Force actions in a chemical, biological, radiological, and nuclear (CBRN) defense Environment. ATD outcomes area designed to continue optimizing S&T solutions, demonstrate how maturing technologies can support prioritized operational needs, enhance transition of cutting edge CBRN technologies and mitigate transition risk by demonstrating operational utility.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Plan and execute the first ATD under the Tenacious Dragon Campaign that will demonstrate developmental technologies and gather warfighter feedback on capabilities that enable the effective employment and layering of CBRN awareness, understanding, protection and mitigation capabilities across medical and non-medical portfolios to provide rapid and effective reduction of the operational impact of CBRN hazards. - Leverage the Services' Future Operating Concepts into the scenario development. - Demonstrate technologies from Defense Threat Reduction Agency (DTRA) Technology Divisions to accelerate and optimize their development, maturation, and transition coordinated with other technologies, enhancing capability development and Doctrine, Organization, Training, Materiel, Leadership and education, Personnel, Facilities and Policy (DOTMLPF-P) updates early in the Research & Development (R&D) cycle. - Expand warfighter participation to include a broad spectrum of warfighters from the Services. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Continue Tenacious Dragon Campaign ATD. - Demonstrate developmental technologies and gather warfighter feedback on capabilities that enable the effective employment and layering of CBRN awareness, understanding, protection and mitigation capabilities across medical and non-medical portfolios to provide rapid and effective reduction of the operational impact of CBRN hazards. - Demonstrate novel technologies from Defense Threat Reduction Agency (DTRA) Technology Divisions to accelerate and optimize their development, maturation, and transition coordinated with other technologies, enhancing capability development and DOTMLPF-P updates early in the Research & Development (R&D) cycle. | - | 6.043 | 5.943 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2022 | FY 2023 | FY 2024 |
| <ul style="list-style-type: none"> - Coordinate an active pathway for developmental technologies from Technology Concepts and User Assessment (e.g. CBOA) thrust areas to ATDs, where appropriate, to demonstrate feedback-based progress in increasingly complex environments and facilitate technology transitions. - Continue the expansion of the service participation to include participation from the Services. <p>FY 2023 to FY 2024 Increase/Decrease Statement: Minor change due to routine program adjustments.</p> | | | | |
| <p>Title: 6) Technology Concept</p> <p>Description: Initiatives prior to and during the development of S&T prototypes that “tease out” and confirm operational requirements, explore utility including potential applications among the Services and scope future S&T programs with Warfighter stakeholders, including Combat Developers and Service representatives. Results from these experiments shape Operating Concepts, doctrine, and materiel systems requirements for the future Joint Force and inform technology developers about potential Warfighter utility of emerging technologies and technology concepts for subsequent portfolio investment. Activities in this area focus on Surveys, User Groups, Table Top Exercises (TTXs), and practical demonstration or User feedback workshops to develop Use Cases, desired operational capabilities, key attributes and explore Concepts of Employment to assess feasibility/ utility of emerging technologies and concepts.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Conduct 4-6 technology concept studies, workshops or Focus Groups including the continuation of distributed sensing and mitigation techniques. Additional technology concepts will be identified within this timeframe based upon technology discovery, maturity, and application to Warfighter needs. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Explore select technology concepts from an operational perspective across all capability areas. Tech Concepts explore the utility and application of technological approaches. These include autonomous operations; enhanced biothreat detection; CB threat diagnosis; improvements to sensitivity, specificity, and the limit of detection for CB sensors; features of biosensors to inform therapeutic or medical countermeasure decisions and treatment; next generation respiratory or physical protection; collective protection guidelines and techniques; and coating concepts for porous surfaces. - Continue to conduct User Feedback Tents for Tech Concepts (Concepts Tents) leveraging User community to identify potential areas for improvement and/or employment of emerging technologies. - Continue series of targeted questionnaires/surveys, facilitated focus groups, workshops and TTXs to define use cases, desired operational capabilities, key attributes and concepts of employment that inform tech development and investment strategies, | | - | 0.300 | 1.496 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) EN3 / <i>Enabling Investments (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| Operating Concepts and materiel requirements. Concept Tent reports provide tech recommendations for more detailed Tech Concept studies/experiments. | | | |
| <i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> Increase due to change in program/project technical parameters. | | | |
| <i>Title:</i> 7) User Assessment | - | 1.949 | 1.851 |
| <i>Description:</i> User Assessments examine maturing technologies and provide opportunities for early Warfighter input into the form, fit, and function of maturing S&T prototypes and technologies; and as appropriate, assess them within a simulated operational environment. The assessments serve as baselines for future ATD programs, and drive S&T gap analysis for key customers and partners. User assessments are characterized by TTXs, Early User Assessments, Technical demonstrations and field experiments that provide candid feedback focused on applicability, utility and recommended improvements while exploring system limitations, vulnerabilities and technology tradeoff analyses of innovative technologies in a non-attributional environment. | | | |
| <i>FY 2023 Plans:</i> - Continue the annual CB Operational Analysis (CBOA) event. | | | |
| <i>FY 2024 Plans:</i> - Continue the annual CBOA event. | | | |
| <i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> Minor change due to routine program adjustments. | | | |
| Accomplishments/Planned Programs Subtotals | - | 39.540 | 43.196 |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
| • EN4: <i>Enabling Investments (ACD&P)</i> | - | 6.781 | 47.272 | - | 47.272 | 51.579 | 9.792 | 9.840 | 9.840 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
|--|--|---|
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) ET3 / <i>Emerging Threats (ATD)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|------------------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| ET3: <i>Emerging Threats (ATD)</i> | - | 0.000 | 0.000 | 10.000 | 0.000 | 10.000 | 10.000 | 10.000 | 10.000 | 10.000 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

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

Individual efforts in this Project include:

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

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

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

| | FY 2022 | FY 2023 | FY 2024 |
|---|---------|---------|---------|
| <p>Title: 1) Emerging Threat Innovation</p> <p>Description: The Chemical and Biological Defense Emerging Threat Innovation Fund challenges DoD Labs and innovation cells to deliver transformational technologies against emerging threats that enables the force to compete, deter, and win in strategic environments described in the National Defense Strategy.</p> <p>FY 2024 Plans: Initiate enhanced capability to more rapidly characterize, and the development of medical countermeasures against, emerging chemical and biological threats through investment in high throughput technologies. Support development of challenges advancing concept and technology development.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement:</p> | - | - | 10.000 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) ET3 / <i>Emerging Threats (ATD)</i> |

| | | | |
|---|----------------|----------------|----------------|
| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
| FY24 provides funding to address future concepts and innovative technology development. | | | |
| Accomplishments/Planned Programs Subtotals | - | - | 10.000 |

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

| Line Item | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|---|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| • CA4: <i>Contamination Avoidance (ACD&P)</i> | 37.189 | - | - | - | - | - | - | - | - | 0.000 | 37.189 |
| • DE4: <i>Decontamination (ACD&P)</i> | 14.747 | - | - | - | - | - | - | - | - | 0.000 | 14.747 |
| • IP4: <i>Individual Protection (ACD&P)</i> | 4.748 | - | - | - | - | - | - | - | - | 0.000 | 4.748 |
| • MT4: <i>Mitigate (ACD&P)</i> | - | 17.302 | 28.785 | - | 28.785 | 20.885 | 15.433 | 13.369 | - | Continuing | Continuing |
| • PT4: <i>Protect (ACD&P)</i> | - | 175.219 | 179.158 | - | 179.158 | 135.096 | 107.341 | 123.538 | 139.376 | Continuing | Continuing |
| • UN4: <i>Understand (ACD&P)</i> | - | 52.708 | 61.638 | - | 61.638 | 64.399 | 48.874 | 41.264 | 38.169 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
|--|--|--|
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) CB3 / <i>Chemical Biological Defense (ATD)</i> |
|--|--|--|

| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| CB3: <i>Chemical Biological Defense (ATD)</i> | - | 28.484 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 28.484 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | - | - |

A. Mission Description and Budget Item Justification

Project CB3 develops technology advancements for joint service application in the areas of digital battlespace management technologies, protection/ hazard mitigation and detection. These activities will speed maturing of advanced technologies to reduce risk in system-oriented integration/demonstration efforts. After FY 2022, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. CB3 efforts in FY 2022 progress to Projects MT3, PT3, and UN3. This restructuring provides standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

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

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

| | FY 2022 | FY 2023 | FY 2024 |
|---|---------|---------|---------|
| <p>Title: 1) Distributed CB Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/ collection systems that are rugged, rapid and accurate. Early indications from capabilities under CB Reconnaissance will allow for enhanced warning of threats.</p> | 1.344 | - | - |
| <p>Title: 2) Enhanced/Emerging Biothreat Sensing</p> <p>Description: Establish robust capability to assess emerging and enhanced biological threats to rapidly develop biosensors for detecting emerging or enhanced biological threats. Quickly develop adaptable, analyte-agnostic laboratory and field-forward detection capabilities to provide a spectrum of improved detection assets for novel threats. This thrust area leverages multi-omics data science or the combining multiple measurements to inform rational and rapid design and development of biodetection</p> | 2.849 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) CB3 / <i>Chemical Biological Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| solutions. Synthetic biological concepts will be thoroughly evaluated and exploited for the development of biosensing solutions and refinement of laboratory methods. | | | |
| Title: 3) Expeditionary Analytical Toolkit (ExAnT) Description: Develop a suite of expeditionary chemical sensors to provide the warfighter with modernized detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards. | 2.598 | - | - |
| Title: 4) Unattended Perimeter Monitoring Description: Establish a layered defense capability by developing and implementing automated and integrated technologies enabling unattended monitoring for chemical and biological threats. These technologies will provide early warning of vapor, aerosol, solid, and liquid hazards and unencumber the Warfighter by reducing logistics and operator burden. Providing a reliable detect-to-warn capability at fixed or expeditionary sites will enhance the overall protective posture of ground and maneuver forces as robust technologies can be miniaturized for portability and operational sustainment. | 1.094 | - | - |
| Title: 5) Unconventional Detection Modalities Description: Utilize a targeted set of programs pushing the boundaries of sensor development by pulling technologies developed from academia and basic research to be integrated into early detection prototypes. These technologies focus on keeping the warfighter ahead of the chemical and biological threats with portable, low SWaP detectors that will protect the general forces and enhance operations on the battlefield by providing warning and field analytics. | 0.781 | - | - |
| Title: 6) CBRN Battlespace Surveillance, Alerting & Response Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. The Joint Science & Technology Office (JSTO) will expand on developing predictive CB exposure algorithms based on non-invasively collected human biomarkers. Current predictive algorithms in development by JSTO are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity. | 4.848 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) CB3 / <i>Chemical Biological Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>Title: 7) CBRN Decision Aids</p> <p>Description: In order to unencumber the warfighter at the tactical edge, continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards.</p> <p>Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> | 1.400 | - | - |
| <p>Title: 8) CBRN Situational Awareness</p> <p>Description: To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled.</p> <p>Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models. Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield.</p> <p>JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems. JSTO will further enhance hazard modeling by creating a seamless indoor- to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy.</p> <p>JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from</p> | 4.264 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects. | | | |
| Title: 9) Air Purification Enhancements Description: This effort supports the Expeditionary Collective Protection (CP). Existing CP systems have high life cycle costs driven by maintenance and limited service life. Science & Technology efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection. | 0.287 | - | - |
| Title: 10) All-Hazards & Respiratory Protection Description: This effort supports the Respiratory and Ocular Protection. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit Self-Contained Breathing Apparatus. | 0.814 | - | - |
| Title: 11) Dynamic Multifunction Materials for Second Skin Description: This effort supports the Percutaneous Protection. Efforts will utilize responsive technologies to provide CB protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments. | 1.313 | - | - |
| Title: 12) Enhanced Survivability Coatings Description: This effort supports the Materiel Contamination Mitigation. Military equipment coatings are challenging and logistically intensive to decontaminate. Efforts within this thrust seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level. | 0.345 | - | - |
| Title: 13) Equipment Decontamination Description: This effort supports the Materiel Contamination Mitigation. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal | 0.649 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) CB3 / <i>Chemical Biological Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| use; and develop improved realistic test methods. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements. | | | |
| Title: 14) Lightweight Protective Garments Description: This effort supports the Percutaneous Protection. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments. | 0.144 | - | - |
| Title: 15) Multifunctional Materials for Protection Description: This effort supports the Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Materiel Contamination Mitigation, and Personnel Contamination Mitigation. Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents. | 1.040 | - | - |
| Title: 16) Personnel Decontamination Description: This effort supports the Personnel Contamination Mitigation. Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a Chemical Warfare Agent (CWA) exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations. | 4.714 | - | - |
| Accomplishments/Planned Programs Subtotals | 28.484 | - | - |

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

| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • CA4: Contamination Avoidance (ACD&P) | 37.189 | - | - | - | - | - | - | - | - | 0.000 | 37.189 |
| • DE4: Decontamination (ACD&P) | 14.747 | - | - | - | - | - | - | - | - | 0.000 | 14.747 |
| • MT4: Mitigate (ACD&P) | - | 17.302 | 28.785 | - | 28.785 | 20.885 | 15.433 | 13.369 | - | Continuing | Continuing |

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) CB3 / <i>Chemical Biological Defense (ATD)</i> |
|--|--|--|

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

| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|---|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • TT4: <i>Technology Transition (ACD&P)</i> | 0.740 | - | - | - | - | - | - | - | - | 0.000 | 0.740 |
| • UN4: <i>Understand (ACD&P)</i> | - | 52.708 | 61.638 | - | 61.638 | 64.399 | 48.874 | 41.264 | 38.169 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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| | | | | | | | | | | | | |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|-------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | | | | | | | | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603384BP / Chemical and Biological Defense Program - Advanced Development | | | | Project (Number/Name) NT3 / Non-Traditional Agents Defense (ATD) | | | |
| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| NT3: Non-Traditional Agents Defense (ATD) | - | 10.843 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 10.843 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

Project NT3 develops future capabilities against emerging and novel threats and verifies current capabilities against Non-Traditional Agents (NTAs). This project focuses on demonstrating fast and agile scientific responses to enhance or develop capabilities that address emerging threats. This project is a comprehensive and focused effort for developing NTA defense capabilities, coordinated with specific interagency partners for doctrine, equipment, and training for the Warfighter and civilian population for defense against NTAs. This project supports advanced technology development of NTA defense science and technology initiatives and transitioning to advance development. After FY 2022, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. NT3 efforts in FY 2022 progress to Project UN3. This restructuring provides standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

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

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

| | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| Title: 1) Distributed CB Reconnaissance | 2.407 | - | - |
| Description: : Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate. | | | |
| Title: 2) Expeditionary Analytical Toolkit (ExAnT) | 6.613 | - | - |
| Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards. | | | |
| Title: 3) Unconventional Detection Modalities | 1.823 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) NT3 / <i>Non-Traditional Agents Defense (ATD)</i> |

| | | | |
|--|----------------|----------------|----------------|
| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
| Description: Develop disruptive technologies to identify unknown or emerging chemical threats and develop chemical sensors that can operate in complex threat environments with high fidelity. This thrust area supports other thrust areas and as needed the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance). | | | |
| Accomplishments/Planned Programs Subtotals | 10.843 | - | - |

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

| <u>Line Item</u> | <u>FY 2022</u> | <u>FY 2023</u> | <u>FY 2024</u> <u>Base</u> | <u>FY 2024</u> <u>OCO</u> | <u>FY 2024</u> <u>Total</u> | <u>FY 2025</u> | <u>FY 2026</u> | <u>FY 2027</u> | <u>FY 2028</u> | <u>Cost To</u> <u>Complete</u> | <u>Total Cost</u> |
|--|----------------|----------------|-------------------------------|------------------------------|--------------------------------|----------------|----------------|----------------|----------------|-----------------------------------|-------------------|
| • CA4: Contamination Avoidance (ACD&P) | 37.189 | - | - | - | - | - | - | - | - | 0.000 | 37.189 |
| • DE4: Decontamination (ACD&P) | 14.747 | - | - | - | - | - | - | - | - | 0.000 | 14.747 |
| • IP4: Individual Protection (ACD&P) | 4.748 | - | - | - | - | - | - | - | - | 0.000 | 4.748 |
| • MT4: Mitigate (ACD&P) | - | 17.302 | 28.785 | - | 28.785 | 20.885 | 15.433 | 13.369 | - | Continuing | Continuing |
| • PT4: Protect (ACD&P) | - | 175.219 | 179.158 | - | 179.158 | 135.096 | 107.341 | 123.538 | 139.376 | Continuing | Continuing |
| • UN4: Understand (ACD&P) | - | 52.708 | 61.638 | - | 61.638 | 64.399 | 48.874 | 41.264 | 38.169 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program **Date:** March 2023

| | | |
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| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) TM3 / <i>Techbase Medical Defense (ATD)</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
|--|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| TM3: <i>Techbase Medical Defense (ATD)</i> | - | 144.779 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 144.779 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | - | - |

A. Mission Description and Budget Item Justification

Project TM3 supports preclinical and early phase clinical development of vaccines, therapeutic drugs, and diagnostic capabilities to provide safe and effective medical defense against validated biological threat agents or emerging infectious disease biothreats including bacteria, toxins, and viruses. After FY 2022, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. TM3 efforts in FY 2022 progress to Projects EN3, MT3, PT3, and UN3. This restructuring provides standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this project include:

- Innovative biotechnology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to biological threat agents will be evaluated.
- Rapid development of medical countermeasure solutions is a crucial modernization strategy to avoid technological surprise against an expanding and sophisticated biological weapons of mass destruction (WMD) threat. Techbase Medical Defense (ATD), therefore, supports the Discovery of Medical Countermeasures Against New and Emerging (DOMANE) threat thrust, which is designed to develop technologies that support understanding, mitigating, and protecting against new and emerging biological threats to include viral, bacterial, and biotoxins.
- Supports the advanced development of medical countermeasures to include prophylaxes, pretreatments, antidotes and therapeutic drugs against new and emerging biological threats. Demonstration of safety and toxicity data through adaptive trials for repurposed U.S. Food & Drug Administration (FDA) approved drugs, novel broad-spectrum drugs and drug combinations supporting submitting Investigational New Drug (IND) processes or Emergency Use Authorizations (EUA). Additionally, this effort supports development of technologies that protect, mitigate and understand new and emerging threats by forecasting pathogenesis and toxicity, structural determinations utilizing high throughput systems to identify both host and pathogen targets using advanced Artificial Intelligence (AI) and a curated repository of high-resolution 3D macromolecular structures to generate drug candidates.
- Leverage lessons learned to shorten future emergency response timelines, mitigate impacts of biological threat outbreaks, and create interim capabilities to protect the warfighter. Leveraging interagency, industry, and academia partnership to build the warfighter's bio-armor to protect against biological threat families. Develop alternative vaccine platform technologies and manage awards utilizing go/no-go checkpoints along the development pathway.

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

| | FY 2022 | FY 2023 | FY 2024 |
|--|---------|---------|---------|
| Title: 1) Battlefield Readiness - Chemical and Biological Incidence Preparedness and Response (CBIPR) | 4.400 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) TM3 / <i>Techbase Medical Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| <p>Description: Provide innovative capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care. Develop field forward medical diagnostics that allow for multiplexed detection of biological and toxin threats. Leverage immunodiagnostics to identify specific targets using current or novel approaches to enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure.</p> | | | |
| <p>Title: 2) Diagnostic Building Blocks - Chemical and Biological Incidence Preparedness and Response (CBIPR)</p> <p>Description: The Diagnostic Building Blocks thrust area lays a foundation for the entire diagnostics portfolio by exploiting areas such as machine learning (ML), synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat.</p> | 2.751 | - | - |
| <p>Title: 3) Emerging Threats - Chemical and Biological Incidence Preparedness and Response (CBIPR)</p> <p>Description: Advance the diagnosis of emerging and/or low prevalence but high threat biological agents leveraging novel technologies. Develop threat agnostic tests based on host biomarkers that identify known or emerging bacterial or viral infections. Characterize markers for antibiotic resistance or susceptibility to identify challenging threats and inform treatment decisions. Improve capabilities to identify diverse biological agents that are not well characterized using molecular or immunodiagnostic approaches.</p> | 3.851 | - | - |
| <p>Title: 4) Medical Countermeasures Initiative</p> <p>Description: The Chemical Biological Incident Preparedness and Response-Medical Countermeasures Initiative (CBIPR-MCMI) will integrate advances in regulatory science and flexible manufacturing technologies and processes; and develop animal models and drug discovery and evaluation platforms as enablers of the advanced development of CBDP medical countermeasure products. These initiatives will lead to the establishment of multi-use platforms and animal models that can be leveraged during a CBRN response to accelerate medical product development and/or regulatory approval as well as reduce overall development costs.</p> | 21.593 | - | - |
| <p>Title: 5) Medical Countermeasures Initiative - Validated Nucleic Acid Vaccine Construction</p> <p>Description: Prototype pan-viral medical countermeasure for the protection against new and highly transmissible viruses. This effort will leverage DOD and other interagency partners to develop MCMs for protection against a panel of transmissible viruses with existing innovative commercial molecular and synthetic biology technology.</p> | 7.430 | - | - |
| <p>Title: 6) Battlefield Readiness</p> | 9.437 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) TM3 / <i>Techbase Medical Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| <p>Description: Develop platforms to prepare the Warfighter with rapid and easy to use diagnostics tests to make sure they are healthy and ready for movement. Platforms developed with affinity-based identification of either pathogen or host response to the pathogen may leverage immunodiagnostics to identify specific targets using antibodies, or explore other innovative approaches. This will enable broader and more accurate diagnosis for a range of targets and across a wider window following exposure. Investments in this area will provide capabilities to the Warfighter that increase the speed of relevancy, enhance troop preparedness, aid with triage support, and provide diagnosis at lower roles of care.</p> | | | |
| <p>Title: 7) Chemical Diagnostics</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional CWAs, including pharmaceutical based agents. Coordinate with the Intelligence Community (IC) to understand the chemical threat space, adapting capabilities to meet the need.</p> | 5.371 | - | - |
| <p>Title: 8) Clinical Evaluation</p> <p>Description: Optimize the diagnostic development pathway by incorporating independent testing and evaluation for more informed prototype transition prior to advanced development. Investments in this area allow evaluation of diagnostic platforms through real world, austere environment testing. This area maintains access to research sites that offer native populations exposed to diseases of interest that would affect the Warfighter in battlefield settings, and provides the ability to acquire novel technologies and provide analytical testing, evaluation, and reach back support for technologies already fielded.</p> | 4.871 | - | - |
| <p>Title: 9) Diagnostic Building Blocks</p> <p>Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats in days instead of weeks.</p> | 6.456 | - | - |
| <p>Title: 10) Emerging Threats</p> <p>Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of</p> | 3.134 | - | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) TM3 / <i>Techbase Medical Defense (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty. | | | |
| <p>Title: 11) Bacterial/Viral/Toxin/Broad Spectrum Prophylaxis</p> <p>Description: The ultimate protection of the warfighter is by pretreating the warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the warfighter to work in a less restrictive environment, absent of any personal protective equipment allowing operation at peak performance. Investments in this Program Element supports de-risking of candidates for transition into advanced development and includes: manufacturing process development, pre-clinical studies for lead candidates to allow initiation of clinical work, regulatory science to support clinical initiation, animal model development for U.S. Food & Drug Administration (FDA) animal rule licensure, and Phase 1 clinical trials. Candidates transition into advanced development once the Phase 1 clinical trial is complete.</p> | 30.411 | - | - |
| <p>Title: 12) Internal COVID - VSV SARS CoV-2 vaccine</p> <p>Description: Provide the warfighter with protection against Coronavirus Disease 2019 (COVID-19) through the development of a SARS-CoV-2 VSV vaccine.</p> | 5.100 | - | - |
| <p>Title: 13) Bacterial Therapeutics</p> <p>Description: Identify, optimize and evaluate potential therapeutic compounds effective against bacterial threat agents.</p> | 13.886 | - | - |
| <p>Title: 14) Toxin Therapeutics</p> <p>Description: Discover and develop therapeutic countermeasures to protect the warfighter against biotoxin threats.</p> | 0.250 | - | - |
| <p>Title: 15) Viral Therapeutics</p> <p>Description: Identify, optimize and evaluate potential therapeutic candidates effective against designated viral threat agents.</p> | 13.887 | - | - |
| <p>Title: 16) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter non-traditional agents (NTAs) and emerging chemical threats to protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability. Successful prophylactics will rapidly detoxify a broad spectrum of compounds of interest (COIs).</p> | 3.352 | - | - |
| <p>Title: 17) Pharmaceutical Based Agents (PBAs)</p> <p>Description: Focuses on therapeutic and proactive strategies to effectively minimize injuries and/or death resulting from exposure to Pharmaceutical Based Agents (PBAs). This will allow the Warfighter to maintain operational capacity in a chemically contested</p> | 4.065 | - | - |

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| battlefield scenario. This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment and pretreatment against chemical warfare injury. | | | |
| Title: 18) Reactivators of AChE as Therapeutics (ReACT) Description: The warfighter requires rapid acting medical countermeasures (MCMs) to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation. Efforts in this area are focused on formulation development and pre-clinical studies for potential candidates that will ultimately be submitted for U.S. Food and Drug Administration (FDA) licensure or previously licensed products for new uses in the treatment of chemical warfare casualties. | 4.534 | - | - |
| Accomplishments/Planned Programs Subtotals | 144.779 | - | - |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| Line Item | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| • EN3: <i>Enabling Investments (ATD)</i> | - | 39.540 | 43.196 | - | 43.196 | 43.198 | 44.449 | 44.449 | 44.449 | Continuing | Continuing |
| • EN4: <i>Enabling Investments (ACD&P)</i> | - | 6.781 | 47.272 | - | 47.272 | 51.579 | 9.792 | 9.840 | 9.840 | Continuing | Continuing |
| • MB4: <i>Medical Biological Defense (ACD&P)</i> | 46.791 | - | - | - | - | - | - | - | - | 0.000 | 46.791 |
| • MT3: <i>Mitigate (ATD)</i> | - | 86.157 | 100.791 | - | 100.791 | 89.511 | 91.704 | 85.795 | 85.480 | Continuing | Continuing |
| • PT3: <i>Protect (ATD)</i> | - | 32.113 | 29.261 | - | 29.261 | 48.969 | 42.794 | 46.159 | 52.581 | Continuing | Continuing |
| • PT4: <i>Protect (ACD&P)</i> | - | 175.219 | 179.158 | - | 179.158 | 135.096 | 107.341 | 123.538 | 139.376 | Continuing | Continuing |
| • UN3: <i>Understand (ATD)</i> | - | 68.415 | 83.825 | - | 83.825 | 81.392 | 87.384 | 73.515 | 71.015 | Continuing | Continuing |

Remarks

D. Acquisition Strategy

N/A

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|---|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|-------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | | | | | | | | | Date: March 2023 | | |
| Appropriation/Budget Activity 0400 / 3 | | | | | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | | | | Project (Number/Name) TT3 / <i>Technology Transition (ATD)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| TT3: <i>Technology Transition (ATD)</i> | - | 7.589 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 7.589 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

Project TT3 validates high-risk/high-payoff technologies, concepts-of-operations, and a Joint Combat Developer concept development and experimentation process to significantly improve Warfighter capabilities in preparation for transition of mature chemical and biological (CB) defense technologies to advanced development programs. This project addresses the three primary chemical and biological defense thrust areas of Assess, Protect, and Mitigate with an emphasis on Integrated Early Warning (IEW) and Integrated Layered Defense (ILD). IEW is conducted through a coordinated program approach focused on layering chemical and biological detection technologies and integrating CB threat indicators, providing a combination of awareness and understanding that facilitates effective decision making so the force can continue military operations and achieve mission success in a CBRN environment. The ILD achieves solutions for capability gaps across medical and non-medical commodity areas to enable warfighter survival and rapid recovery in a CBRN environment. After FY 2022, the Chemical Biological Defense Program (CBDP) RDT&E Projects were restructured to align with the CBDP portfolio construct. TT3 efforts in FY 2022 progress to Project EN3. This restructuring provides standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

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

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

| | FY 2022 | FY 2023 | FY 2024 |
|--|----------------|----------------|----------------|
| Title: 1) Advanced Technology Demonstration | 4.640 | - | - |
| Description: Advanced Technology Demonstrations (ATDs) facilitate Warfighters and other operational stakeholders' participation in field demonstrations that evaluate integrated technologies or prototype systems with demonstrated technical performance in high fidelity and realistic operating environments. Building on the technology concepts and user assessments thrust areas conducted earlier in the technology maturation process, feedback from the Warfighters during ATDs ensures that these technologies are operationally relevant, value added, and can be matured and potentially transitioned in a timely and effective manner to S&T Managers or transition partners for advanced development and employment across the spectrum of Joint Force actions in a CBRN Defense Environment. In some cases, ATD residuals are left with ATD operating units for extended user | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2024 Chemical and Biological Defense Program | | Date: March 2023 |
| Appropriation/Budget Activity 0400 / 3 | R-1 Program Element (Number/Name) PE 0603384BP / <i>Chemical and Biological Defense Program - Advanced Development</i> | Project (Number/Name) TT3 / <i>Technology Transition (ATD)</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2022 | FY 2023 | FY 2024 |
|---|----------------|----------------|----------------|
| evaluations which provides additional real world data to technology developers. ATD outcomes area designed to enhance transition of cutting edge CBRN technologies and mitigate transition risk by demonstrating operational utility and initial Technics, Tactics and Procedures. | | | |
| Title: 2) Technology Concept Description: Initiatives to validate technology requirements and scope future S&T programs with Warfighter stakeholders, including Combat Developers and Service representatives. Results from these experiments shape Operating Concepts, doctrine, and materiel systems requirements for the future Joint Force and inform technology developers about potential Warfighter utility of emerging technologies and technology concepts for subsequent portfolio investment. Activities in this area focus on Surveys, User Groups, Table Top Exercises (TTXs), and practical demonstration or User feedback workshops to develop Use Cases, desired operational capabilities, key attributes and explore Concepts of Employment to assess feasibility/utility of emerging technologies. | 1.296 | - | - |
| Title: 3) User Assessment Description: User Assessments examine maturing technologies and provide opportunities for early Warfighter input into the form, fit, and function of maturing S&T prototypes and technologies; and as appropriate, assess them within a simulated operational environment. The assessments serve as baselines for future Advanced Technology Demonstration (ATD) programs, and drive S&T gap analysis for key customers and partners. User assessments are characterized by TTXs, Early User Assessments, Technical demonstrations and field experiments that provide candid feedback focused on applicability, utility and recommended improvements while exploring system limitations, vulnerabilities and technology tradeoff analyses of innovative technologies in a non-attributional environment. | 1.653 | - | - |
| Accomplishments/Planned Programs Subtotals | 7.589 | - | - |

| C. Other Program Funding Summary (\$ in Millions) | | | | | | | | | | | |
|--|----------------|----------------|-------------------------|------------------------|--------------------------|----------------|----------------|----------------|----------------|-----------------------------|-------------------|
| Line Item | FY 2022 | FY 2023 | FY 2024 Base | FY 2024 OCO | FY 2024 Total | FY 2025 | FY 2026 | FY 2027 | FY 2028 | Cost To Complete | Total Cost |
| • TT4: <i>Technology Transition (ACD&P)</i> | 0.740 | - | - | - | - | - | - | - | - | 0.000 | 0.740 |

Remarks

D. Acquisition Strategy
N/A