| Exhibit R-2, RDT&E Budget Item Justification: PB 2025 Chemical and Biological Defense Program | Date: March 2024 |
|---|---|
| **Appropriation/Budget Activity**<br>0400: *Research, Development, Test & Evaluation, Defense-Wide* / BA 4: *Advanced Component Development & Prototypes (ACD&P)* | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* |

| COST ($ in Millions) | Prior Years | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Total Program Element | 0.000 | 246.531 | 316.853 | 304.374 | 0.000 | 304.374 | 269.933 | 235.581 | 218.377 | 214.706 | Continuing | Continuing |
| UN4: *Understand (ACD&P)* | - | 52.163 | 61.638 | 53.120 | 0.000 | 53.120 | 47.808 | 49.646 | 49.608 | 62.105 | Continuing | Continuing |
| PT4: *Protect (ACD&P)* | - | 170.788 | 179.158 | 172.190 | 0.000 | 172.190 | 154.024 | 131.577 | 137.660 | 120.758 | Continuing | Continuing |
| MT4: *Mitigate (ACD&P)* | - | 16.935 | 28.785 | 43.364 | 0.000 | 43.364 | 44.601 | 36.558 | 5.309 | 11.643 | Continuing | Continuing |
| EN4: *Enabling Investments (ACD&P)* | - | 6.645 | 47.272 | 35.700 | 0.000 | 35.700 | 23.500 | 17.800 | 25.800 | 20.200 | Continuing | Continuing |

**A. Mission Description and Budget Item Justification**

This program element (PE) resources Advanced Component Development and Prototypes across the Understand, Protect, Mitigate, and Enabling Investments portfolios. Program efforts validate high-risk/high-payoff technologies and their respective concepts of operations for significant improvement to Warfighter capabilities in preparation for the transition of mature technologies to advanced development programs requiring chemical and biological (CB) defense technologies. Chemical 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 support component and subsystem maturity prior to integration in major, complex systems and may involve risk reduction initiatives and include technology demonstrations. This effort facilitates transitions of Integrated Early Warning and Integrated Layered Defense products. FY25 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 (UN4): Maintain effort in distinguishing between bacterial, viral, and toxin diagnostics. Update detector libraries for relevant detection and identification systems. Continue efforts to integrate detection capabilities into Service combat platforms. Develop detection and diagnostic technologies with compatibility to receive and transmit sensor data on Service networks. Identify Service concepts for Integrated Early Warning (IEW) and maintain cyber compliance of fielded Chemical Biological Radiological and Nuclear (CBRN) information systems.

- Protect (PT4): Continued efforts to unencumber the warfighter by delivering improved personal protection capabilities that incorporate inherent survivability into Service equipment and platforms and which offer protection against the diverse threat agents that near-peer adversaries are developing. Develop capability for next-generation individual protective equipment. In collaboration with Biomedical Advanced Research and Development Authority (BARDA), develops and tests monoclonal antibody medical countermeasures through Phase 1 clinical trials as an accelerated antibodies program. Develops a robust computational toolset/prototype database intended to decrease product development risk throughout the drug development life cycle, accelerate candidate development, and enable preemptive preparedness and rapid response. Leveraging the Advanced Development Manufacturing Network, delivers the ability to rapidly develop Medical Countermeasures (MCMs) against emerging or known chemical/biological threats by establishing mature platform technologies that allow for rapid response. Develops plague monoclonal antibody-based medical

countermeasure prototype through Phase 1 clinical testing. Continues work to deliver prototype nucleic acid-based vaccines for three CBRN and two potential pandemic threats through non-clinical and human Phase I clinical trials.

- Mitigate (MT4): Sustain efforts in antiviral therapeutics. Develop capabilities to incorporate the use of in silico and Machine Learning/Artificial Intelligence technologies for drug discovery and development. Increase efforts regarding platform technologies. Development of repurposing pharmaceuticals that enable a rapid response capability to combat emerging threats. Supports the development of robot decontamination platform systems. Completes prototype development for a sprayable slurry Science & Technology (S&T) transition to decontaminate hardened and sensitive equipment, such as weapon system optics, electronic equipment and spot decontamination on vehicles. Continues prototype development for S&T transitions for tactical temporary coatings that mitigate the effects of a CBRN attack by protecting assets from the effects of chemical warfare agents.

- Enabling Investments (EN4): Development of efforts to evaluate integrated technologies or prototype systems in high fidelity and realistic operating environment, including system-specific efforts that help expedite technology transition from the laboratory to operational use. Increase efforts to improve integration of collective protection into Service major combat platforms.

The projects in this PE support the advanced component technology development phase of the DoD acquisition system and are therefore correctly placed in Budget Activity 4.

| B. Program Change Summary ($ in Millions) | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total |
|---|---|---|---|---|---|
| Previous President's Budget | 252.010 | 316.853 | 271.959 | - | 271.959 |
| Current President's Budget | 246.531 | 316.853 | 304.374 | - | 304.374 |
| Total Adjustments | -5.479 | 0.000 | 32.415 | - | 32.415 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | - | - | | | |
| • SBIR/STTR Transfer | -5.479 | - | | | |
| • Other Adjustments | - | - | 32.415 | - | 32.415 |

**Change Summary Explanation**

Funding: FY 2023 (-$5.479 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts.

FY 2025 ($32.415 Million): (+$31.519 Million) Increase supports enhanced biodefense efforts supporting accelerated medical countermeasure (MCM) development and efforts to reduce risk to the regulatory path for FDA approval for Antiviral Oral Therapeutics and Botulinum Toxin Therapeutics, and inflation rate adjustments (+$0.896 Million).

| Exhibit R-2, RDT&E Budget Item Justification: PB 2025 Chemical and Biological Defense Program | Date: March 2024 |
|---|---|
| **Appropriation/Budget Activity**<br>0400: *Research, Development, Test & Evaluation, Defense-Wide I* BA 4: *Advanced Component Development & Prototypes (ACD&P)* | **R-1 Program Element (Number/Name)**<br>PE 0603884BP *I Chemical and Biological Defense Program - Dem/Val* |

Schedule: N/A

Technical: Provides for critical new start programs Agent-Directed Therapeutics (AD TX) and the Medical Decontamination Personnel Skin (MED DECON PS).
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| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | | | | | | | | | | Date: March 2024 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 4 | | | | | R-1 Program Element (Number/Name)<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | | | | Project (Number/Name)<br>UN4 / *Understand (ACD&P)* | | | |
| **COST ($ in Millions)** | **Prior Years** | **FY 2023** | **FY 2024** | **FY 2025 Base** | **FY 2025 OCO** | **FY 2025 Total** | **FY 2026** | **FY 2027** | **FY 2028** | **FY 2029** | **Cost To Complete** | **Total Cost** |
| UN4: *Understand (ACD&P)* | - | 52.163 | 61.638 | 53.120 | 0.000 | 53.120 | 47.808 | 49.646 | 49.608 | 62.105 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

**A. Mission Description and Budget Item Justification**

The Understand Advanced Component Development and Prototypes (ACD&P) Project provides the Joint Force the ability to continually receive information about the Chemical Biological Radiological and Nuclear (CBRN) situation at a desired time and place by detecting, identifying, and quantifying CBRN hazards in air, water, or on land, and on personnel, equipment or facilities. Efforts also develop a clear understanding of the current and predicted CBRN situation; collect, query, and assimilate information from sensors in real time to inform decisions and provide impacts of CBRN hazards.

Efforts included in this Project are:

(1) Advanced Differential Diagnostics (ADD)
(2) Advanced Emerging Threat Defense (AET DEFENSE)
(3) Biological Defense Improvement Program (BDIP)
(4) Non-Targeted Sequencing Identification System (NSIS)
(5) Physiological Monitoring Sensor Suite (PM2S)
(6) Colorimetric Indicator (C-IND)
(7) Chemical Biological Radiological Nuclear Support to Command and Control (CSC2)
(8) Compact Vapor Chemical Agent Detector (CVCAD)
(9) Proximate Chemical Agent Detector (PCAD)
(10) Surveillance and Pathogen Characterization-Enhanced Biological Defense (SPCHAR-ENBD)

The Advanced Differential Diagnostics (ADD) is a new start program in FY24 and will determine if an individual has likely been infected and the nature of that infection, during early stages of illness for unknown threats, including biological warfare agents and emerging infectious diseases. ADD will provide timely feedback for disease prevention in operational environments, by quickly identifying warfighters who may have contracted illness. In FY25, the ADD program will continue Technology Maturation and Risk reduction for ADD candidate technologies.

The Advanced and Emerging Threat Defense (AET Defense) program continues to address the highest priority CBRN gaps and supports the CBDP Strategic Line of Effort to meet current and emerging threats by anticipating chemical and biological hazards and identifying capabilities to counter emerging and future threats. The AET Defense program collaborates with the Joint Services and interagency to align RDT&E resources to determine readiness against emerging threats as they are identified across the entire CBDP enterprise portfolio. In FY25 and beyond, AET Defense activities continue to focus on demonstrating and evaluating technologies to assess performance against emerging threats.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

The Biological Defense Improvement Program (BDIP) will enhance the set of biodefense capabilities to significantly improve its ability to rapidly understand, prevent, prepare for, respond to, and recover from a vast array of future biological threats. BDIP will support the Department of Defense (DoD) CBDP mission with rapid prototyping capabilities to understand, and protect against threats. BDIP will address joint and service gaps and priorities related to biodefense, and will develop and execute a biodefense strategy. It considers the Biological Warfare threat and vulnerabilities to give biodefense the agility and speed necessary to provide relevant, effective, affordable, and sustainable capabilities that can be ubiquitously deployed on the battlefield against current, emerging and future biological threats. The DoD with academia, industry and other interagency departments will partner to gain opportunities to accelerate technology, adopt surge capacity, and advance consumable and alternative solution across the entire Biodefense portfolio. BDIP transitions efforts to the Non-Targeted Sequencing Identification System (NSIS), Wearable All Hazard Remote Monitoring Program (WARP), Far Forward Biological Sequencing (FFBS), and the Physiological Monitoring Sensor Suite (PM2S) programs in FY24.

The Non-targeted Sequencing Identification System (NSIS) provides a commercially available, rapid biological sequencing capability with the potential to identify an unlimited number of biological warfare agents (BWA), including emerging, engineered, or enhanced organisms. NSIS reduces identification time from days to hours, enabling decision support to all Command echelons. The NSIS is a small, portable device equipped with consumable flow cells that are small, electronic chips for processing the biological sample. NSIS identifies biological anomalies and translates the data on a laptop computer, enabling fast and effective mitigation and protection for the force. This capability can determine whether the enemy is using synthetic biology for the purpose of thwarting traditional medical countermeasures or current detection/identification devices. FY25 funding will award contracts for prototyping, conduct developmental tests, and complete soldier touchpoints.

The Physiological Monitoring Sensor Suite (PM2S) is a new start program in FY24. It develops CBRN exposure software algorithms that analyze physiological data collected from wearable sensors. These algorithms provide commanders with actionable information to maximize warfighter readiness, performance, and enhance resiliency before, during, and after CBRN operations. FY25 BA4 efforts finish development of a joint service algorithm software environment that enables the integration, packaging, and DoD-wide deployment of algorithms transitioned from DTRA JSTO and service wearables S&T partners. This software environment will install on the hardware-focused Chemical and Biological Wearables - Enhanced Biodefense (CB WEARABLES-ENBD) solution set, which will provide an additional layer of sensing to rapidly detect CBRN threats across the joint forces, decrease risk to mission, and risk to force.

The Colorimetric Indicator Kit (C-IND) is a new start program in FY24 and will provide improved hazard detection and classification performance with reduced false alarm rate, and potential for integration onto unmanned platforms. The intent of this package is to provide the General Forces a low-cost, easy to use, higher confidence liquid, solid and vapor hazard detection capabilities for traditional and emerging chemical hazards. These improved decisions will reduce casualties and improve the combat effectiveness of troops engaged in conflicts involving the use of chemical hazards. C-IND will ease the warfighter from current training and operational burden. FY25 funding will fund program development, technology readiness assessment, and program management support. This will include coordination with Defense Threat Reduction Agency (DTRA) on awarding contracts for C-IND in the Science and Technology (S&T) efforts that will transition to technology maturation risk reduction (TMRR) in the future. FY25 will also support the development of a draft capability development document (CDD) for C-IND.

The CBRN Support to Command and Control (CSC2) is the overarching System of Systems (SoS) software that provides for the interoperability and integration of CBRN and non-CBRN sensors to achieve needed situational awareness and understanding to accomplish CBRN integrated layered defense, interdependent with Service Computing Environments. CSC2 will establish Service and Joint All Domain Command and Control (JADC2) compatible CBRN Common Operating Environment (COE)

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

architecture and deployment environments. FY25 maintains the continuous engineering of the currently fielded CBRN information systems and synchronization for the sunset of these capabilities with the deployment of CSC2.

Compact Vapor Chemical Agent Detector (CVCAD) is an unobtrusive, low-profile chemical detection capability that will continuously, and autonomously, monitor and alert general and specialized units to an unsafe environment without further burdening the warfighters payload or interfering with the primary mission. The CVCAD will warn CBRN and non-CBRN forces of Chemical Weapon Agent (CWA), Toxic Industrial Chemical (TIC), or confined space hazards to inform immediate force protection decisions. The small form factor (less than 2 pounds) is amenable to both man-worn and unmanned aerial or ground system operations to enable timely personnel protective action and other force protection decisions.

The Proximate Chemical Agent Detector (PCAD) is developing a Non-Trace and Trace capabilities. Non-Trace will provide the services with a handheld point and interrogate device that identifies visible liquid and solid chemical threats on surfaces at standoff (non-contact) distances. The PCAD Trace will provide the services with a handheld device that will rapidly scan an area to locate, detect and identify non-visible solid and liquid threats on surfaces at standoff (non-contact) distances.

The Surveillance and Pathogen Characterization-Enhanced Biodefense (SPCHAR-ENBD) will utilize Pathogenicity Studies to investigate development of disease of CBRN threat agents and verify usefulness of these disease models. Results from these studies will be utilized to identify targets for MCM (Medical Countermeasures) development, testing, and identify groups of CBRN threat agents that can be treated by broad-spectrum MCMs. The program will complete work on Botulinum Neurotoxin and pivot to address Henipavirus in FY25.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Title:*** 1) ADD | - | 9.987 | 9.747 |
| ***Description:*** Product development and product management.<br><br>***FY 2024 Plans:***<br>Issue Request for Project Proposals, award Other Transaction Authority project agreements, and initiate development and evaluation of prototype solutions.<br><br>***FY 2025 Plans:***<br>Continue to develop and evaluate prototype diagnostic candidates.<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to product management cost efficiencies following contract award and acquisition milestones. | | | |
| ***Title:*** 2) AET DEFENSE | 2.736 | 6.629 | 7.183 |
| ***Description:*** AET Defense activities will focus on demonstrating and evaluating technologies to assess performance against emerging threats.<br><br>***FY 2024 Plans:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Continue efforts to address emerging biological threats. Begin evaluation and assessment of ability to detect and mitigate three additional threat classes. Update spectral libraries and hazard data management tools to incorporate emerging threat information. Produce additional data to better assess detection and defensive capabilities against new requirements and inform rapid fielding decisions. Conduct three tabletop exercises on three additional threat materials to support Joint Service and interagency tactics, techniques, and procedures (TTP) development and gap analysis for materiel solutions. Monitor market surveys and assessments of technologies for rapid fielding by the CBDP to mitigate defensive capability gaps as emerging threats are identified.<br>***FY 2025 Plans:***<br>Continue efforts to produce additional data to better assess detection and decontamination capabilities against toxins, bioregulators, and other advanced threats. Conduct workshops on understanding advanced and emerging threat priorities to align with the CBDP. Conduct market surveys and assessments of technologies for rapid fielding by Chemical Biological Defense Program to mitigate emerging threat gaps as threats are identified.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to significant increase in quantity of emerging threats being assessed for impacts simultaneously. Increase also due to a more thorough understanding of all defensive capabilities, not just sensors, against emerging threats. | | | |
| ***Title:*** 3) BDIP<br>***Description:*** Genomic sequencing in support of Non-Targeted Sequencing Identification System (NSIS) and Far-Forward Biological Sequencing (FFBS) Programs of Record. | 2.350 | - | - |
| ***Title:*** 4) NSIS<br>***Description:*** Product development, test and evaluation, support costs, and Program Office management.<br>***FY 2024 Plans:***<br>Conduct initial verification and validation of commercial-off-the-shelf genomic sequencing devices, purchase Oxford Nanopore Technologies MinION Mk1C genomic sequencing devices, and assess military utility for the National Guard Bureau, US Navy, and US Marine Corps. Continue user feedback trials with the National Guard Bureau Civil Support Teams. Funds will pay for program labor, office management, and administrative processes to include (but not limited to) program oversight, resource justification, budgeting and programming, milestone and schedule tracking.<br>***FY 2025 Plans:*** | - | 0.653 | 1.760 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Funding supports contract awards for prototyping, conducting developmental tests, and completing soldier touchpoints. Funds will also support program labor, office management, and administrative processes to include (but not limited to) program oversight, resource justification, budgeting and programming, milestone and schedule tracking.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to support contract awards and required test activities to inform a Milestone B decision in 1QFY26. | | | |
| ***Title:*** 5) PM2S<br>***Description:*** Algorithm Deployment Environment<br>***FY 2024 Plans:***<br>PM2S will develop and conduct software hardening on chemical and biological defense physiological monitoring algorithms to enable capabilities to be deployed on a number of service-sponsored hardware architectures.<br>***FY 2025 Plans:***<br>Continue to develop and conduct software hardening on chemical and biological defense physiological monitoring algorithms, after completion of the technical data package, to enable capabilities to be deployed on a number of service-sponsored hardware architectures.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to completing the plan to build a joint service algorithm software environment. | - | 1.200 | 5.100 |
| ***Title:*** 6) C-IND<br>***Description:*** Program Development, technology readiness, and program management support.<br>***FY 2024 Plans:***<br>Initiate and conduct table top exercises to inform stakeholder's of requirements and fund technology maturation risk reduction (TMRR) testing activities.<br>***FY 2025 Plans:***<br>Plan and prepare technology readiness experiment, and program management support services. Coordinate with Defense Thread Reduction Agency (DTRA) on science and technology (S&T) efforts for C-IND.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase in line with program schedule requirements to conduct activities supporting technology readiness. | - | 1.043 | 1.638 |
| ***Title:*** 7) CSC2 | 32.677 | 28.039 | 26.092 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Description:*** CSC2 Execution Phase of Software Acquisition pathway, and Continuous Software Development, Integration, and Delivery<br><br>***FY 2024 Plans:***<br>Continue to develop CBRN applications to support: CBRN hazard warning, reporting, analysis, and prediction; CBRN impact modeling: and Decision Support Tools. Continue the development of a Cloud-Native Software architecture for the interoperability between CBRN sensors, CBRN applications, and Service computing environments. Start a software development pipeline using Development, Security, Operations (DevSecOps) leveraging existing DoD DevSecOps infrastructure. Continue cybersecurity testing and operational testing in support of verifying the iterative, agile software to deliver Minimal Viable Capability Releases (MVCR).<br>***FY 2025 Plans:***<br>Complete initial Minimum Viable Capability Release (MVCR) for CSC2. Continue agile Test & Evaluation and continuous engineering for follow-on capability releases.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to reduction of software development activities. | | | |
| ***Title:*** 8) CVCAD<br>***Description:*** Prototype Advanced Development, Testing & Program Management<br><br>***FY 2024 Plans:***<br>Finalization of system design to complete Milestone B. Activities will include milestone documentation, developmental testing and program office management and administration processes to include program oversight, resource justification, budgeting and programming, milestone and schedule tracking.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program/project transitioned to Engineering and Manufacturing Development Phase. | 12.985 | 3.600 | - |
| ***Title:*** 9) PCAD<br>***Description:*** PCAD developmental testing, program management and contract support for Non-Trace.<br><br>***FY 2024 Plans:***<br>Transition breadboard prototypes from DTRA/Joint Science Technology Office to continue in the Technology Maturation Risk Reduction phase. Conduct advanced developmental testing of prototypes to execute an early user feedback assessment to | 0.900 | 8.487 | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| include development testing with troops to support Milestone B plan in FY25. Continue program management and support activities to transition technologies from Science and Technology development to acquisition.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease in FY25 due to PCAD Non-Trace transitioning to engineering and manufacturing development. | | | |
| ***Title:*** 10) SPCHAR-ENBD<br>***Description:*** Pathogenicity Studies.<br>***FY 2024 Plans:***<br>Initiate studies to investigate CBRN threat pathogenesis and/or pathogenicity models.<br>***FY 2025 Plans:***<br>Continue studies to investigate CBRN threat pathogenesis and/or pathogenicity models.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to alignment with program acquisition strategy. | 0.515 | 2.000 | 1.600 |
| **Accomplishments/Planned Programs Subtotals** | 52.163 | 61.638 | 53.120 |

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

| Line Item | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • UN5: *Understand (SDD)* | 128.837 | 182.726 | 154.658 | - | 154.658 | 124.463 | 90.423 | 63.185 | 55.658 | Continuing | Continuing |
| • UN7: *Understand (Op Sys Dev)* | 39.602 | 50.603 | 59.296 | - | 59.296 | 71.995 | 70.339 | 64.131 | 59.948 | Continuing | Continuing |
| • SA0054: *Advanced Differential Diagnostics (ADD)* | - | - | - | - | - | - | - | 0.687 | - | Continuing | Continuing |
| • SA0053: *Bio Defense Improvement Program (BDIP)* | - | - | - | - | - | 4.458 | 17.200 | 32.944 | 31.293 | Continuing | Continuing |
| • SA0050: *Chemical Biological Radiological Nuclear Support to Command and Control (CSC2)* | 11.803 | 2.186 | 2.257 | - | 2.257 | 2.366 | 2.451 | 2.549 | 2.603 | Continuing | Continuing |
| • SA0024: *Compact Vapor Chemical Agent Detector (CVCAD)* | - | - | - | - | - | 8.200 | 13.687 | 22.144 | 22.144 | Continuing | Continuing |

**Remarks**

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

**D. Acquisition Strategy**

Advanced Differential Diagnostics (ADD)

The Advanced Differential Diagnostics (ADD) program will utilize Other Transaction Authorization (OTA) project agreements to identify, competitively prototype, and mature commercial solutions deemed technologically viable, and evaluate them in as realistic an operational environment as possible. Successful candidate systems will transition to the Engineering and Manufacturing Development phase to be further developed under the OTA agreement, in order to satisfy military and U.S. Food & Drug Administration (FDA) regulatory requirements for subsequent production and fielding to the Services.

Advanced and Emerging Threat Defense (AET DEFENSE)

The AET DEFENSE program will use a variety of acquisition approaches to survey, assess, and rapidly field technologies to inform and fill advanced and emerging threat defense capability gaps. The program will use existing Multiple Award Indefinite Delivery Indefinite Quantify Task Order Contracts to provide technical support to studies and assessments of performance against emerging threats. For Program of Record (PoR) systems currently in development that will be assessed for performance against emerging threats, those PoR's existing contracts will be modified to incorporate development engineering and test support for emerging threat capability. The AET Defense program will utilize OTAs for system development and prototyping activities and Government Agencies and Federally Funded Research and Development Centers to provide development, testing, and technical support.

Non-targeted Sequencing Identification System (NSIS)

Non-targeted Sequencing Identification System (NSIS) will leverage commercial technology using the existing General Services Administration (GSA) Urgent Commercial-Off-the-Shelf (COTS) and Sustainment Contract. NSIS will purchase test articles during developmental phases, and production-representative articles during Production and Deployment phase (Low Rate Initial Production and Full Rate Production). The program will leverage existing validated Joint Capabilities Integration and Development System (JCIDS) documents to streamline the acquisition process. The NSIS program is approved to be an Acquisition Category (ACAT) IV program and is anticipated to enter at Milestone A.

Physiological Monitoring Sensor Suite (PM2S)

PM2S will leverage a rapid acquisition strategy (such as the software acquisition pathway) to develop, integrate, and field software algorithms into hardware-focused decision support tools developed under the CB WEARABLES-ENBD program. These capabilities will help to address knowledge gaps identified under the FY23 OSD-sponsored wearables Pilot program related to integrated physiological threat-based decision support.

Colorimetric Indicator (C-IND)

The C-IND program is an approved Acquisition Category (ACAT) IV program anticipated to enter into acquisition following receipt of draft Service requirements and the transition of the Defense Threat Reduction Agency (DTRA) science and technology development. The acquisition strategy is still being refined; however the program will

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

work with DTRA and will use the Combating Weapons of Mass Destruction Other Transactional Authority (CWMD-OTA) contract to transition technologies from Science and Technology to Acquisition. The systems will be developed with the intent to be consumable item that would be ordered through the government supply system with an issued National Stock Number.

Chemical Biological Radiological Nuclear Support to Command and Control (CSC2)

CSC2 is executed through the Software Acquisition Pathway, leveraging existing Information Technology Box requirements and Capability Needs Statements (CNS) furnished through the Services and Combatant Commands. CSC2 is executing a modular contracting approach, where the use of Other Transaction Authorities (OTAs), and Indefinite Delivery/Indefinite Quantity (IDIQ) will be used to meet agile software objectives of continuous development, integration, delivery, and engineering. CSC2 will establish a Service and Joint All-Domain Command and Control (JADC2) compatible CBRN Common Operating Environment (COE) architecture and leverage existing enterprise Develop Security Operations (DevSecOps) efforts to facilitate continuous and iterative delivery of capability to the Joint Force through the development of a unified software solution.

Compact Vapor Chemical Agent Detector (CVCAD)

The CVCAD program will use the Combating Weapons of Mass Destruction Other Transaction Authority (CWMD OTA) contract vehicle to transition four technologies from Science & Technology (S&T) into the program of record. This streamlined acquisition approach is broken into four phases; Phase I S&T advanced development, Phase II technology transition maturation evaluation, Phase III competitive prototyping down select, Engineering decision, manufacturing and development. Phase IV will execute Production and Development for low rate initial production (LRIP) systems. CVCAD will procure full rate production (FRP) items through a follow-on Federal Acquisition Regulation based contract.

Proximate Chemical Agent Detector (PCAD)

Proximate Chemical Agent Detector (PCAD) Non-Trace effort will leverage the existing Science & Technology (S&T) Chemical Weapons of Mass Destruction (CWMD) Other Transaction Authority (OTA) contract in FY24 to procure prototypes for Technology Maturation Risk Reduction (TMRR) phase. This streamlined approach will use one contracting mechanism to transition technology from S&T to acquisition and allow follow-on acquisitions up through Low Rate Initial Production (LRIP). PCAD Non-Trace will procure Full Rate Production (FRP) items through a follow-on Federal Acquisition Regulation based contract. PCAD Trace is a future effort that will leverage the existing S&T CWMD OTA's to evaluate and transition the technologies in accordance with the Technology Transition Agreement (TTA) with the Defense Threat Reduction Agency in FY27. PCAD Non-Trace intends to enter in at a Milestone B (MS B) 1QFY25 utilizing the existing Next Generation Chemical Detector (NGCD) Milestone A (MS A) Acquisition Decision Memorandum (ADM).

Surveillance and Pathogen Characterization - Enhanced Biological Defense (SPCHAR-ENBD)

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

SPCHAR ENBD is an investment program that will leverage interagency partners and existing contracts to investigate disease progression and measure biomarkers of selected CBRN threat agents to inform medical defense against biological warfare threats. The tailored acquisition pathway will allow flexibility to counter new and emerging biothreats.

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* | |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADD - HW C - Product Management | Various | Various : N/A | - | 0.000 | | 1.938 | Dec 2023 | 1.878 | Dec 2024 | - | | 1.878 | Continuing | Continuing | 0.000 |
| ADD - HW C - Product Development | C/CPFF | TBD : N/A | - | 0.000 | | 6.950 | Mar 2024 | 6.954 | Dec 2024 | - | | 6.954 | Continuing | Continuing | 0.000 |
| AET DEFENSE - HW C - Emerging threat detection/ decontamination/protection capability prototyping | MIPR | Various : N/A | - | 0.444 | Feb 2023 | 0.888 | Jan 2024 | 1.066 | Feb 2025 | - | | 1.066 | Continuing | Continuing | 0.000 |
| AET DEFENSE - HW C - Detection/Decon/ Protection | MIPR | Various : N/A | - | 0.844 | May 2023 | 0.750 | Feb 2024 | 0.000 | | - | | 0.000 | 0.000 | 1.594 | 0.000 |
| AET DEFENSE - SW C - Hazard awareness tool updates | MIPR | Various : N/A | - | 0.500 | Apr 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.500 | 0.000 |
| AET DEFENSE - HW C - Emerging Threat Detection | C/CPFF | Johns Hopkins University - Applied Physics Laboratory : Laurel, MD | - | 0.000 | | 0.600 | Apr 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.600 | 0.000 |
| BDIP - HW S - Government Labor and SME Support | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC) : Rock Island, IL | - | 0.895 | Apr 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.895 | 0.000 |
| BDIP - HW S - Genomic Sequencing - NGB | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC) : Aberdeen Proving Ground, MD | - | 0.655 | Apr 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.655 | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* | |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| NSIS - HW C - COTS Oxford Nanopore MinION Genomic Sequencers and Flow Cells | MIPR | TBD : N/A | - | 0.000 | | 0.215 | Dec 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.215 | 0.000 |
| NSIS - ES C - OGA Matrix Labor | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC) : Aberdeen Proving Ground, MD | - | 0.000 | | 0.108 | Dec 2023 | 0.150 | Dec 2024 | - | | 0.150 | Continuing | Continuing | 0.000 |
| NSIS - HW C - Advanced Prototype Development | Various | Various : N/A | - | 0.000 | | 0.000 | | 0.947 | Dec 2024 | - | | 0.947 | Continuing | Continuing | 0.000 |
| PM2S - SW C - Algorithm Deployment Environment (Analytics Engine) | FFRDC | Various : N/A | - | 0.000 | | 1.000 | Dec 2023 | 4.017 | Dec 2024 | - | | 4.017 | Continuing | Continuing | 0.000 |
| C-IND - ES C - Program Support Costs | Various | Various : N/A | - | 0.000 | | 0.075 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.075 | 0.000 |
| C-IND - HW S - Initial Product Planning | Various | Various : N/A | - | 0.000 | | 0.664 | Nov 2023 | 0.642 | Nov 2024 | - | | 0.642 | Continuing | Continuing | 0.000 |
| C-IND - HW C - Product Development Team Labor | Various | Various : N/A | - | 0.000 | | 0.000 | | 0.642 | Nov 2024 | - | | 0.642 | Continuing | Continuing | 0.000 |
| CSC2 - SW S - Product Development Team Labor | Various | Various : N/A | - | 7.285 | Mar 2023 | 2.028 | Dec 2023 | 5.245 | Nov 2024 | - | | 5.245 | Continuing | Continuing | 0.000 |
| CSC2 - SW S - Operational Capability | C/CPAF | Various : N/A | - | 19.725 | May 2023 | 11.869 | Dec 2023 | 10.728 | Apr 2025 | - | | 10.728 | Continuing | Continuing | 0.000 |
| CSC2 - SW S - Contractor Product Development Team Labor | Various | Various : N/A | - | 0.000 | | 1.846 | Dec 2023 | 0.000 | | - | | 0.000 | 0.000 | 1.846 | 0.000 |
| CSC2 - SW S - Service CoE and CE Convergence | MIPR | Various : N/A | - | 0.000 | | 1.200 | Dec 2023 | 0.000 | | - | | 0.000 | 0.000 | 1.200 | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* | |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CVCAD - HW S - Advanced Prototype Development | C/FFP | Advanced Technologies International : Summerville, SC | - | 8.477 | Sep 2023 | 1.620 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 10.097 | 0.000 |
| PCAD - ES S - Advanced Prototype Development | C/FFP | Advanced Technologies International : Summerville, SC | - | 0.000 | | 4.808 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 4.808 | 0.000 |
| PCAD - HW S - Government Team Labor | Various | Various : N/A | - | 0.301 | Mar 2023 | 0.581 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.882 | 0.000 |
| SPCHAR-ENBD - SW GFPP - Pathogenicity Studies | Various | Various : N/A | - | 0.515 | Apr 2023 | 1.678 | Dec 2023 | 1.290 | Dec 2024 | - | | 1.290 | Continuing | Continuing | 0.000 |
| SPCHAR-ENBD - SW GFPP - Direct Product Support | Various | Various : N/A | - | 0.000 | | 0.147 | Dec 2023 | 0.139 | Dec 2024 | - | | 0.139 | Continuing | Continuing | 0.000 |
| | | **Subtotal** | - | 39.641 | | 38.965 | | 33.698 | | - | | 33.698 | Continuing | Continuing | N/A |

**Remarks**

CSC2: Service CE Convergence is part of Operational Capability and was combined in FY25

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AET DEFENSE - ES C - Engineering support to evaluating, assessing, and designing capabilities | MIPR | Various : N/A | - | 0.000 | | 0.465 | Jan 2024 | 1.460 | Dec 2024 | - | | 1.460 | Continuing | Continuing | 0.000 |
| BDIP - TD/D SB - Genomic Sequencing Research Study | MIPR | MRIGlobal : Kansas City, MO | - | 0.566 | Dec 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.566 | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* | |

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PM2S - ES S - Software/ Systems Engineer | MIPR | Various : N/A | - | 0.000 | | 0.000 | | 0.341 | Dec 2024 | - | | 0.341 | Continuing | Continuing | 0.000 |
| CSC2 - ES C - Contractor Support | C/CPFF | Various : N/A | - | 0.000 | | 0.768 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.768 | 0.000 |
| CSC2 - ES C - Support | Various | Various : N/A | - | 1.661 | Mar 2023 | 4.551 | Mar 2024 | 5.039 | Feb 2025 | - | | 5.039 | Continuing | Continuing | 0.000 |
| CVCAD - ES S - OGA Support | MIPR | Various : N/A | - | 0.771 | Jul 2023 | 1.000 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 1.771 | 0.000 |
| PCAD - ES S - OGA Support | MIPR | Various : N/A | - | 0.042 | Aug 2023 | 0.750 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.792 | 0.000 |
| | | **Subtotal** | - | 3.040 | | 7.534 | | 6.840 | | - | | 6.840 | Continuing | Continuing | N/A |

**Test and Evaluation ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| AET DEFENSE - DTE S - Technology Assessments | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC) : Aberdeen Proving Ground, MD | - | 0.517 | Feb 2023 | 1.750 | Jan 2024 | 1.132 | Feb 2025 | - | | 1.132 | Continuing | Continuing | 0.000 |
| AET DEFENSE - DTE C - Technology Assessments | MIPR | Various : N/A | - | 0.000 | | 0.651 | Mar 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.651 | 0.000 |
| AET DEFENSE - DTE S - Technology Assessments | C/CPFF | Johns Hopkins University - Applied Physics Laboratory : Laurel, MD | - | 0.000 | | 0.650 | Apr 2024 | 1.750 | Feb 2025 | - | | 1.750 | Continuing | Continuing | 0.000 |
| AET DEFENSE - DTE C - Market Research | MIPR | Various : N/A | - | 0.000 | | 0.000 | | 1.325 | Feb 2025 | - | | 1.325 | Continuing | Continuing | 0.000 |
| NSIS - DTE C - Prototype Testing | MIPR | Various : N/A | - | 0.000 | | 0.265 | Dec 2023 | 0.425 | Dec 2024 | - | | 0.425 | Continuing | Continuing | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

**Test and Evaluation ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PM2S - DTE S - System DT&E | MIPR | Various : N/A | - | 0.000 | | 0.000 | | 0.163 | Jan 2025 | - | | 0.163 | Continuing | Continuing | 0.000 |
| C-IND - DTE S - Experimental Testing/ Requirement Refinement | Various | Various : N/A | - | 0.000 | | 0.200 | Nov 2023 | 0.000 | Nov 2024 | - | | 0.000 | 0.000 | 0.200 | 0.000 |
| CSC2 - OTE S - Technical/ Operational Demo | MIPR | Various : N/A | - | 1.775 | Mar 2023 | 2.801 | Dec 2023 | 2.117 | Nov 2024 | - | | 2.117 | Continuing | Continuing | 0.000 |
| CVCAD - DTE S - MIL STD/Surety Testing | MIPR | Various : N/A | - | 0.981 | Jan 2023 | 0.620 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 1.601 | 0.000 |
| CVCAD - DTE S - Vapor Testing | MIPR | MRIGlobal : Kansas City, MO | - | 1.100 | Jun 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 1.100 | 0.000 |
| PCAD - DTE S - Testing | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center (CBC) : Aberdeen Proving Ground, MD | - | 0.461 | May 2023 | 1.500 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 1.961 | 0.000 |
| | | **Subtotal** | - | 4.834 | | 8.437 | | 6.912 | | - | | 6.912 | Continuing | Continuing | N/A |

**Management Services ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADD - PM/MS S - Management Services | Various | Various : N/A | - | 0.000 | | 1.099 | Dec 2023 | 0.915 | Dec 2024 | - | | 0.915 | Continuing | Continuing | 0.000 |
| AET DEFENSE - PM/MS S - IPT Support/Program Management | MIPR | U.S. Army Combat Capabilities Development Command (DEVCOM) Chemical Biological Center | - | 0.431 | Dec 2022 | 0.875 | Dec 2023 | 0.450 | Nov 2024 | - | | 0.450 | Continuing | Continuing | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

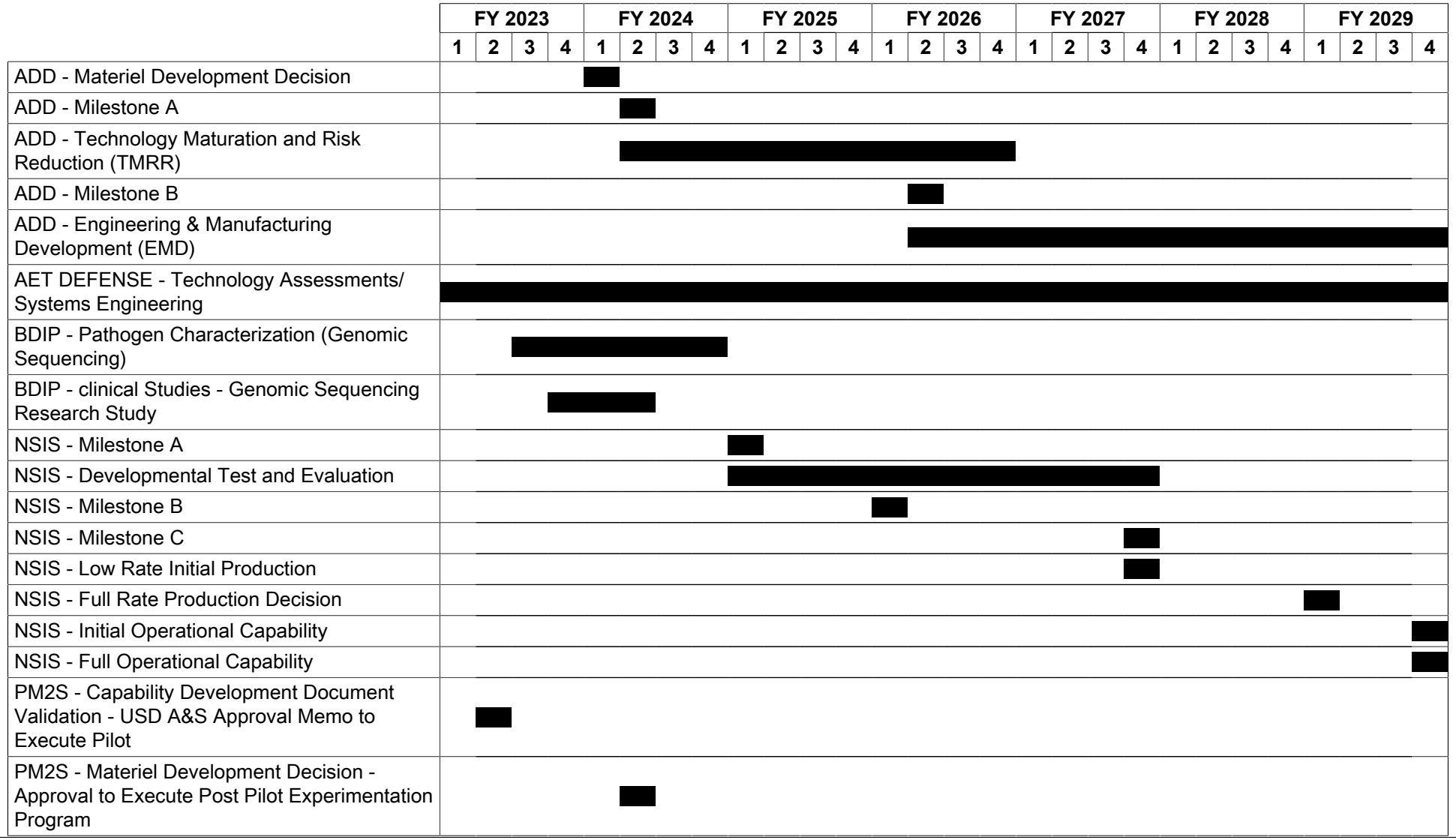
**Management Services ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | (CBC) : Aberdeen Proving Ground, MD | | | | | | | | | | | | | |
| BDIP - PM/MS S - Program Management Support | MIPR | Various : N/A | - | 0.234 | Mar 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.234 | 0.000 |
| NSIS - PM/MS S - Program Management Support | MIPR | Various : N/A | - | 0.000 | | 0.065 | Dec 2023 | 0.238 | Jan 2025 | - | | 0.238 | Continuing | Continuing | 0.000 |
| PM2S - PM/MS C - Management for Algorithm Development | MIPR | Various : N/A | - | 0.000 | | 0.200 | Nov 2023 | 0.579 | Nov 2024 | - | | 0.579 | Continuing | Continuing | 0.000 |
| C-IND - PM/MS C - Program Management Support | Various | Various : N/A | - | 0.000 | | 0.104 | Nov 2023 | 0.354 | Nov 2024 | - | | 0.354 | Continuing | Continuing | 0.000 |
| CSC2 - PM/MS C - Program Management Support | MIPR | Various : N/A | - | 2.231 | Feb 2023 | 2.976 | Nov 2023 | 2.963 | Nov 2024 | - | | 2.963 | Continuing | Continuing | 0.000 |
| CVCAD - PM/MS S - Program Management Support | MIPR | Various : N/A | - | 1.656 | Mar 2023 | 0.360 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 2.016 | 0.000 |
| PCAD - PM/MS S - Program Management | MIPR | Various : N/A | - | 0.096 | Jul 2023 | 0.848 | Nov 2023 | 0.000 | | - | | 0.000 | 0.000 | 0.944 | 0.000 |
| SPCHAR-ENBD - PM/MS SB - Management Support | Various | Various : N/A | - | 0.000 | | 0.175 | Dec 2023 | 0.171 | Dec 2024 | - | | 0.171 | Continuing | Continuing | 0.000 |
| | | **Subtotal** | - | 4.648 | | 6.702 | | 5.670 | | - | | 5.670 | Continuing | Continuing | N/A |

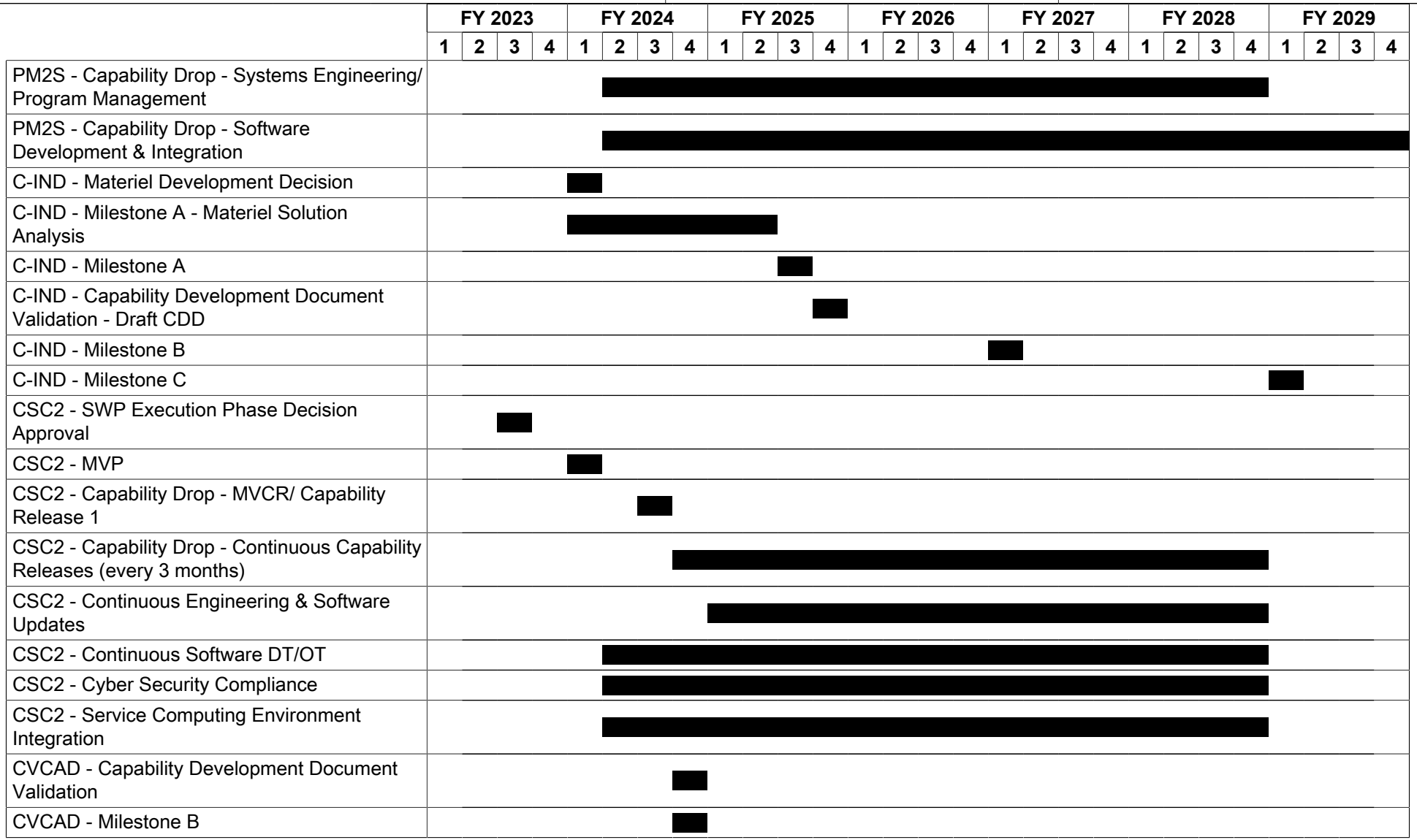
| | Prior Years | FY 2023 | | FY 2024 | | FY 2025 Base | | FY 2025 OCO | | FY 2025 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Project Cost Totals** | - | 52.163 | | 61.638 | | 53.120 | | - | | 53.120 | Continuing | Continuing | N/A |

**Remarks**

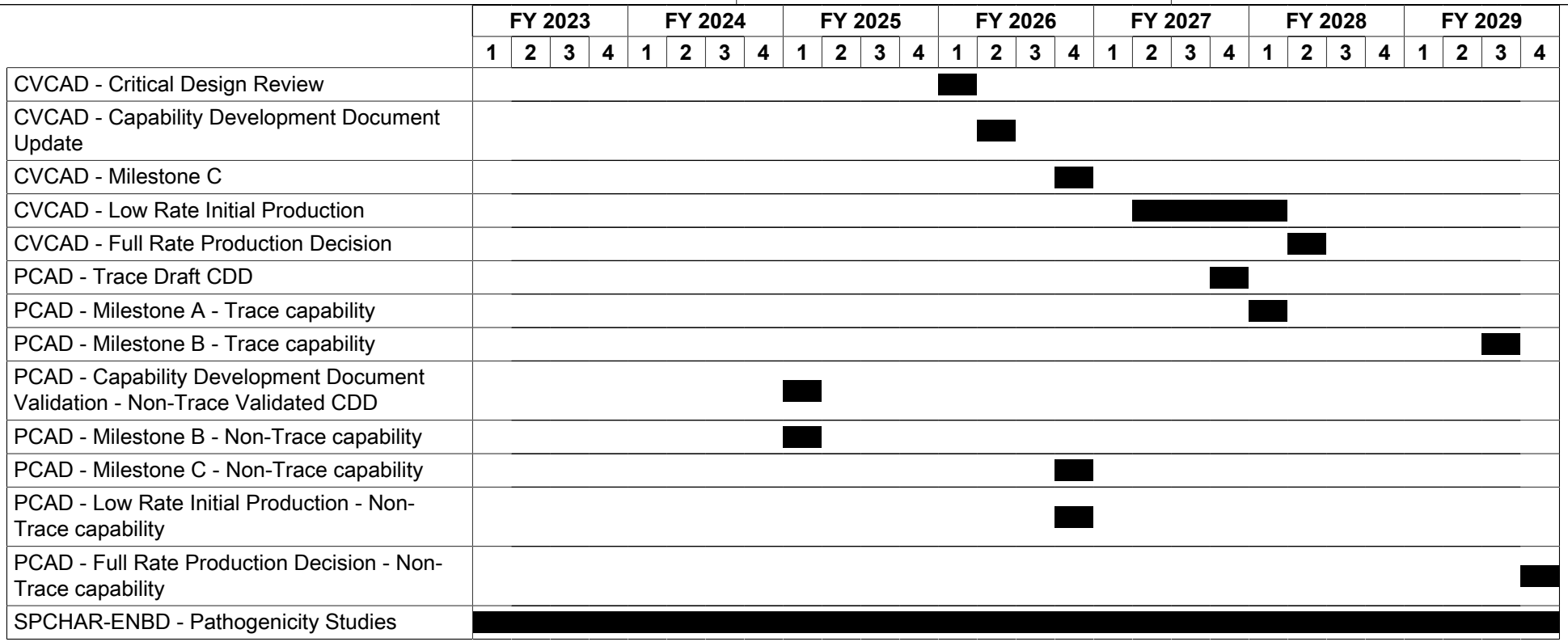
| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |



| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |



| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |



| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

## Schedule Details

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| ADD - Materiel Development Decision | 1 | 2024 | 1 | 2024 |
| ADD - Milestone A | 2 | 2024 | 2 | 2024 |
| ADD - Technology Maturation and Risk Reduction (TMRR) | 2 | 2024 | 4 | 2026 |
| ADD - Milestone B | 2 | 2026 | 2 | 2026 |
| ADD - Engineering & Manufacturing Development (EMD) | 2 | 2026 | 4 | 2029 |
| AET DEFENSE - Technology Assessments/Systems Engineering | 1 | 2023 | 4 | 2029 |
| BDIP - Pathogen Characterization (Genomic Sequencing) | 3 | 2023 | 4 | 2024 |
| BDIP - clinical Studies - Genomic Sequencing Research Study | 4 | 2023 | 2 | 2024 |
| NSIS - Milestone A | 1 | 2025 | 1 | 2025 |
| NSIS - Developmental Test and Evaluation | 1 | 2025 | 4 | 2027 |
| NSIS - Milestone B | 1 | 2026 | 1 | 2026 |
| NSIS - Milestone C | 4 | 2027 | 4 | 2027 |
| NSIS - Low Rate Initial Production | 4 | 2027 | 4 | 2027 |
| NSIS - Full Rate Production Decision | 1 | 2029 | 1 | 2029 |
| NSIS - Initial Operational Capability | 4 | 2029 | 4 | 2029 |
| NSIS - Full Operational Capability | 4 | 2029 | 4 | 2029 |
| PM2S - Capability Development Document Validation - USD A&S Approval Memo to Execute Pilot | 2 | 2023 | 2 | 2023 |
| PM2S - Materiel Development Decision - Approval to Execute Post Pilot Experimentation Program | 2 | 2024 | 2 | 2024 |
| PM2S - Capability Drop - Systems Engineering/Program Management | 2 | 2024 | 4 | 2028 |
| PM2S - Capability Drop - Software Development & Integration | 2 | 2024 | 4 | 2029 |
| C-IND - Materiel Development Decision | 1 | 2024 | 1 | 2024 |

| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| C-IND - Milestone A - Materiel Solution Analysis | 1 | 2024 | 2 | 2025 |
| C-IND - Milestone A | 3 | 2025 | 3 | 2025 |
| C-IND - Capability Development Document Validation - Draft CDD | 4 | 2025 | 4 | 2025 |
| C-IND - Milestone B | 1 | 2027 | 1 | 2027 |
| C-IND - Milestone C | 1 | 2029 | 1 | 2029 |
| CSC2 - SWP Execution Phase Decision Approval | 3 | 2023 | 3 | 2023 |
| CSC2 - MVP | 1 | 2024 | 1 | 2024 |
| CSC2 - Capability Drop - MVCR/ Capability Release 1 | 3 | 2024 | 3 | 2024 |
| CSC2 - Capability Drop - Continuous Capability Releases (every 3 months) | 4 | 2024 | 4 | 2028 |
| CSC2 - Continuous Engineering & Software Updates | 1 | 2025 | 4 | 2028 |
| CSC2 - Continuous Software DT/OT | 2 | 2024 | 4 | 2028 |
| CSC2 - Cyber Security Compliance | 2 | 2024 | 4 | 2028 |
| CSC2 - Service Computing Environment Integration | 2 | 2024 | 4 | 2028 |
| CVCAD - Capability Development Document Validation | 4 | 2024 | 4 | 2024 |
| CVCAD - Milestone B | 4 | 2024 | 4 | 2024 |
| CVCAD - Critical Design Review | 1 | 2026 | 1 | 2026 |
| CVCAD - Capability Development Document Update | 2 | 2026 | 2 | 2026 |
| CVCAD - Milestone C | 4 | 2026 | 4 | 2026 |
| CVCAD - Low Rate Initial Production | 2 | 2027 | 1 | 2028 |
| CVCAD - Full Rate Production Decision | 2 | 2028 | 2 | 2028 |
| PCAD - Trace Draft CDD | 4 | 2027 | 4 | 2027 |
| PCAD - Milestone A - Trace capability | 1 | 2028 | 1 | 2028 |
| PCAD - Milestone B - Trace capability | 3 | 2029 | 3 | 2029 |
| PCAD - Capability Development Document Validation - Non-Trace Validated CDD | 1 | 2025 | 1 | 2025 |
| PCAD - Milestone B - Non-Trace capability | 1 | 2025 | 1 | 2025 |

| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>UN4 / *Understand (ACD&P)* |

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| PCAD - Milestone C - Non-Trace capability | 4 | 2026 | 4 | 2026 |
| PCAD - Low Rate Initial Production - Non-Trace capability | 4 | 2026 | 4 | 2026 |
| PCAD - Full Rate Production Decision - Non-Trace capability | 4 | 2029 | 4 | 2029 |
| SPCHAR-ENBD - Pathogenicity Studies | 1 | 2023 | 4 | 2029 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | | | | | | | | | | Date: March 2024 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 4 | | | | | R-1 Program Element (Number/Name)<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | | | | Project (Number/Name)<br>PT4 / *Protect (ACD&P)* | | | |
| **COST ($ in Millions)** | **Prior Years** | **FY 2023** | **FY 2024** | **FY 2025 Base** | **FY 2025 OCO** | **FY 2025 Total** | **FY 2026** | **FY 2027** | **FY 2028** | **FY 2029** | **Cost To Complete** | **Total Cost** |
| PT4: *Protect (ACD&P)* | - | 170.788 | 179.158 | 172.190 | 0.000 | 172.190 | 154.024 | 131.577 | 137.660 | 120.758 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

**A. Mission Description and Budget Item Justification**

The Protect Advanced Component Development and Prototypes (ACD&P) Project provides the ability to shield the Joint Force from harm caused by Chemical Biological Radiological and Nuclear (CBRN) hazards by preventing or reducing individual and collective exposures, applying prophylaxis to prevent or mitigate negative physiological effects, and protecting critical equipment.

Efforts included in this Project are:

(1) Advanced System for Protection and Integration Reduction of Encumbrances (ASPIRE)
(2) Accelerated Antibodies-Enhanced Biological Defense (AA-ENBD)
(3) Biological Containment Isolation System - Enhanced Biological Defense (BCIS-ENBD)
(4) Generative Unconstrained Intelligent Drug Engineering-Enhanced Biological Defense (GUIDE-ENBD)
(5) Medical Countermeasures Platform Technologies (MCMPT)
(6) Plague Monoclonal Antibodies (PLG MAB)
(7) Portable Patient Transport System - Enhanced Biological Defense (PPTS-ENBD)
(8) Shipboard Isolation System (SIS)
(9) Vaccine Acceleration by Modular Progression-Enhanced Biological Defense (VAMP-ENBD)
(10) Uniform Integrated Protective Ensemble Family of Systems Footwear (UIPE FoS Footwear)
(11) Biological Warfare Defense Medical Countermeasures Prototype (BIOPROTO)

The Advanced System for Protection and Integrated Reduction of Encumbrances (ASPIRE) Next Generation Respirator effort provides respiratory and ocular protection against CBRN threats that allows near normal operations in a CBRN environment by minimizing or eliminating physical and psychological burden and increasing warfighter lethality. This program, in conjunction with work by Joint Science and Technology Office (JSTO), will lay out the strategy and path forward required to minimize the burden to the warfighter while still providing respiratory and ocular protection against CBRN agents. In FY25, funding will be utilized to develop prototypes on a Countering Weapons of Mass Destruction Other Transaction Authority (CWMD OTA).

The Accelerated Antibodies - Enhanced Biodefense (AA-ENBD) will develop prophylactic and therapeutic monoclonal antibody (mAb) Medical Countermeasure (MCM) against a broad range of biological threats. AA-ENBD will target the discovery, identification and small-scale manufacture of mAbs with sufficient material to support non-clinical and clinical testing. Sufficient doses will be produced and maintained for potential use in emergency response situations. AA-ENBD was formerly known as Monoclonal Antibodies Therapeutics-Enhanced Biodefense (MAB TX-ENBD). In FY25 AA-ENBD will complete phase 1 clinical studies for mAb product number 1 and initiate phase 1 trials for mAb products number 2 and number 3.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

The Biological Containment Isolation System - Enhanced Biological Defense (BCIS-ENBD) will provide a negative pressure shelter system for medical treatment of biologically contaminated patients in an Army field hospital environment. BCIS-ENBD will provide a ground-based isolation area for personnel infected or suspected of infection from a biological threat and allows medical staff to monitor and/or treat while decreasing the risk of infecting other patients and staff. This project was funded in FY24 under the Collective Protection CONEX-Enhanced Biological Defense (COL PRO CONEX-ENBD) effort, and was renamed BCIS-ENBD to accurately reflect the capability and applicability of the system. In FY25, BCIS-ENBD will complete concept design, system planning and conduct an initial concept demonstration.

The Generative Unconstrained Intelligent Drug Engineering - Enhanced Biodefense (GUIDE-ENBD) is an intelligent drug design and engineering system intended to decrease product development risk throughout the medical countermeasure development life cycle, accelerate candidate development, and enable preemptive preparedness and rapid response. GUIDE impacts the discovery and design of biologics products (e.g., monoclonal antibodies and vaccines) and small molecule drugs through a multi-faceted optimization process capturing critical quality attributes of safety, efficacy, manufacturability, and pharmacokinetics/pharmacodynamics (PK/PI). Furthermore, GUIDE incorporates computational and experimental approaches to manufacturing controls and preclinical/clinical testing. GUIDE is a collaboration between interagency, academia, and industry partners and is integrated with the Accelerated Antibodies and RNA Vaccine Acceleration by Modular Progression (VAMP) programs. In FY25 GUIDE will continue to develop a fully integrated computational approach to accelerating medical countermeasure development.

The Medical Countermeasure Platform Technologies (MCMPT) program streamlines and accelerates delivery of medical countermeasure to the Warfighter against known and emerging biological threats by establishing mature platform technologies that allow for rapid response and by reducing developmental risks. MCMPT is establishing enabling technologies and prepositioning platform systems within the Department of Defense (DoD)'s Advanced Development Manufacturing (ADM) network using standardized discovery, design, manufacturing, and testing processes to reduce the medical countermeasure (MCM) development risks. In FY25 MCMPT will continue to deliver enduring capabilities from which future candidates can be manufactured.

The Plague Monoclonal Antibodies (PLG MAB) program was transitioned in FY2023 from Medical Countermeasure Platform Technologies (MCMPT) Advanced Development and Manufacturing of Antibody Technology (ADAMANT) effort. PLG MAB will provide a pre-exposure monoclonal antibody product to protect the warfighter from aerosolized plague and is intended for intramuscular route of administration. This capability is complementary to plague therapeutics and will provide a continuum of protection against plague bacteria. In FY25 PLG MAB continues monoclonal antibody discovery and half-life extensions to produce product to support a Phase 1 clinical study.

The Portable Biocontainment Patient Transport System-Enhanced Biodefense (PPTS-ENBD) effort will provide a biocontainment isolation system to safely transport personnel infected or suspected of infection from a biological threat. In FY25, PPTS ENBD will begin system test and evaluation and develop logistics products.

The Shipboard Isolation System (SIS) project will provide the capability to temporarily isolate or quarantine personnel to prevent the spread of a biological threat and safely evacuate patients for transfer off the ship. SIS will be used on multiple Navy ship types to contain and medically monitor/treat patients while protecting embarked crew and personnel. In FY25, SIS will release Request for Proposals (RFP), award contract for prototypes, and delivery of prototypes.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

The Vaccine Acceleration by Modular Progression - Enhanced Biodefense (VAMP-ENBD) will 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, VAMP will continue to build the Warfighter's bio-armor to protect against biological threat families. VAMP will continue to develop alternative vaccine platform technologies and manage awards utilizing go/no-go checkpoints along the development pathway.

The Uniform Integrated Protective Ensemble Family of Systems Footwear (UIPE FoS Footwear) will provide the warfighter with percutaneous protection against liquid, vapor, dust, particulate, or sporulated toxic material, chemical and biological warfare agents and radiological fallout particles when worn as part of the Uniform Individual Protection Ensemble (UIPE). UIPE FOS Footwear funding discontinues after FY24 due to higher priorities within the Chemical Biological Defense Program (CBDP).

BIOPROTO supports early-phase clinical development and supporting non-clinical safety, tolerability and toxicity data for candidate vaccines and therapeutic drugs prior to transition to System Development & Demonstration. This work provides safe and effective medical defense against validated biological threat agents and emerging infectious disease biothreats including bacteria, toxins, and viruses. This work also involves the evaluation of Food and Drug Administration (FDA)-approved therapeutics for operational use, as well as generation of novel drug products and formulations, to enhance level of protection and/or operational utility for the Warfighter. This effort reduces programmatic risk of failure in the advanced development phase.

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Title:*** 1) ASPIRE<br>***Description:*** Next Generation Respirator Development<br>***FY 2025 Plans:***<br>Award initial Other Transaction Authority (OTA) contract to develop prototypes. Down-select of S&T concepts will occur in FY25 with additional technological insertions executed between FY25 and FY28.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase of funds will be used to award prototype OTA | - | - | 1.500 |
| ***Title:*** 2) AA-ENBD<br>***Description:*** Accelerated Antibody Development and Production<br>***FY 2024 Plans:***<br>Initiate phase 1 clinical studies for the first 2 mAb products and complete large-scale manufacturing of 5-10K phase 2 compliant doses to transfer into the Rapid Access to Products In Development (RAPID) program for the first 2 mAb products. Initiate manufacturing scale up and nonclinical testing for mAb product #3. Initiate mAb product #4 in conjunction with GUIDE Live Fire Exercise.<br>***FY 2025 Plans:*** | 57.813 | 67.664 | 42.270 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Accelerate the development, and manufacture of multiple monoclonal antibody medical countermeasures.<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to completion of activities for mAb product #1. | | | |
| ***Title:*** 3) BCIS-ENBD<br><br>***Description:*** Prototype, test and evaluate ground based biocontainment isolation systems.<br><br>***FY 2025 Plans:***<br>Complete closeout activities from concept development demonstration.<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Funds were moved from Project PT5 BCIS-ENBD to better align requirements with budget activity. | - | - | 0.300 |
| ***Title:*** 4) GUIDE-ENBD<br><br>***Description:*** Develop and implement a fully integrated computational approach to accelerating medical countermeasure development.<br><br>***FY 2024 Plans:***<br>Execute medical countermeasure design campaigns to discover prototypes for up to 3 distinct threat families. Iterate the planning, coding, building, and testing of up to 17 new and existing digital tools and algorithms to increase speed and accuracy of computational MCM discovery efforts and rapid response capability; Conduct Live Fire Exercise against an unknown target, countermeasure will be transferred to Accelerated Antibodies program for development and testing.<br><br>***FY 2025 Plans:***<br>Plan, code, build, and test new and existing digital tools and algorithms and corresponding experimental capabilities to increase the speed and accuracy of computational MCM discovery efforts for mAbs, vaccines and small molecules.<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to establishing vaccine specific computational tools and laboratory testing capabilities to support live fire exercise. | 53.894 | 49.633 | 58.291 |
| ***Title:*** 5) MCMPT<br><br>***Description:*** Manufacturing<br><br>***FY 2024 Plans:*** | - | 1.200 | 1.522 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Continue refining Digital Twin Artificial Intelligence models for manufacturing process controls to reduce human interventions and increase process efficiency.<br>***FY 2025 Plans:***<br>Initiate DARPA Nucleic acids on demand Worldwide (NOW), a small-scale manufacturing platform that will enable rapid production of nucleic acid MCM (DNA or RNA) prototypes for initial screening activities, to eliminate need for outsourcing critical prototype manufacturing.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to starting new manufacturing effort. | | | |
| ***Title:*** 6) MCMPT<br>***Description:*** Rapid Response<br>***FY 2024 Plans:***<br>Continue refining Pandemic Prevention Platform (P3) capability to discover/optimize antigens against known and emerging threats to be further developed under AA-ENBD or GUIDE-ENBD programs for monoclonal and vaccine countermeasures and stored within the Rapid Access to Products in Development (RAPID) program.<br>***FY 2025 Plans:***<br>Continue P3 development to improve efficiency and response time of the platform in discovering medical countermeasures against novel threats.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to alignment with development activities and increased efficiencies in each technology. | 10.355 | 5.076 | 4.988 |
| ***Title:*** 7) MCMPT<br>***Description:*** Nucleic Acid<br>***FY 2024 Plans:***<br>Initiate the transfer of DARPA gene-encoded Deoxyribonucleic Acid (DNA) or Ribonucleic Acid (RNA) based medical countermeasure platform. This new technology will enhance both the onset of protection and duration of protection for a pre-exposure countermeasure against chemical/biological threats. Initiate transition of DARPA Nucleic Acid on Demand (NOW) manufacturing capability. This capability eliminates outsourcing of lengthy prototype manufacturing to allow programs such as GUIDE to test and evaluate more candidates real time.<br>***FY 2025 Plans:*** | - | 4.200 | 7.700 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Continue development of Gene Encoded DNA/RNA MCM program and improve delivery system to provide instant and long-lasting protection against viral, bacterial and/or toxin threats. Initiate the transfer of the Alpha prototype from the DARPA Nucleic Acids on Demand Worldwide (NOW) manufacturing effort, a small-scale manufacturing platform to enable rapid production of nucleic acid MCM (DNA/RNA) prototypes for initial screening activities. Initiate Proof of Concept broad spectrum MCM platform technology.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to increased manufacturing activities. | | | |
| ***Title:*** 8) PLG MAB<br>***Description:*** Manufacturing, Non-Clinical and Clinical Development<br>***FY 2024 Plans:***<br>Continue large scale manufacturing to support the Phase I clinical study and delivery of 5-10K doses of Phase 2 compliant material to Rapid Access to Products in Development (RAPID) program for an Interim Fielding Capability. Complete Pharmacokinetics (PK)/Efficacy studies, small animal model toxicology studies and initiate Phase 1 clinical study to support Milestone B in FY25.<br>***FY 2025 Plans:***<br>Complete and deliver 5,000-10,000 doses of PLG MAB product for Phase 2. Continue Phase 1 Study in humans for initial safety evaluation.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to completion of Phase 2 manufacturing efforts. | 12.815 | 14.700 | 9.350 |
| ***Title:*** 9) PPTS-ENBD<br>***Description:*** Prototype, test and evaluate Portable Patient Transport Systems for biocontainment and isolation.<br>***FY 2025 Plans:***<br>Complete closeout activities from concept development demonstration<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Funds were moved from Project PT5 PPTS-ENBD to better align requirements with budget activity. | - | - | 0.300 |
| ***Title:*** 10) SIS<br>***Description:*** Prototype Development and Testing | - | - | 0.300 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***FY 2025 Plans:***<br>Complete closeout activities from concept development demonstration<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Funds were moved from Project PT4 SIS to better align requirements with budget activity. | | | |
| ***Title:*** 11) VAMP-ENBD<br>***Description:*** Manufacturing, non-clinical studies, and clinical trials<br>***FY 2024 Plans:***<br>Continue development and manufacturing of vaccine candidates against multiple viral biothreats. Continue test and evaluation efforts in animals and human clinical trials.<br>***FY 2025 Plans:***<br>Continue development and manufacturing of vaccine candidates against multiple biothreats. Continue test and evaluation efforts in animals and human clinical trials. Initiate plague vaccine/biological response modifier effort.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase to support additional work for plague vaccine/biological response modifier effort. | 33.781 | 34.299 | 45.669 |
| ***Title:*** 12) UIPE FoS Footwear<br>***Description:*** Development of the UIPE FoS Footwear System<br>***FY 2024 Plans:***<br>Initiate prototype Other Transaction Authority (OTA) to evaluate up to ten footwear alternatives, conduct chemical agent swatch testing to inform initial down select of alternatives, conduct limited early user testing to garner feedback on service preferred alternatives.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>UIPE FOS FOOTWEAR funding discontinues after FY24 due to higher priorities within the Chemical Biological Defense Program (CBDP). | - | 2.386 | - |
| ***Title:*** 13) BIOPROTO<br>***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 Food and Drug Administration (FDA)-approved therapeutics are limited or lacking. Research is focused on preclinical evaluation (e.g., in large animal models) of broad-spectrum therapeutic candidates that target pathogen directly, enhance the host response and/or relieve | 2.130 | - | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| BW disease symptoms. Candidates that are shown to be both safe and efficacious against BW threats will advance for further clinical evaluation under RDT&E budget activity 5, and can be accelerated for use against emerging infectious diseases during an outbreak. | | | |
| **Accomplishments/Planned Programs Subtotals** | 170.788 | 179.158 | 172.190 |

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

| Line Item | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • PT3: *Protect (ATD)* | 29.631 | 29.261 | 46.050 | - | 46.050 | 46.703 | 46.159 | 54.536 | 54.535 | Continuing | Continuing |
| • PT5: *Protect (SDD)* | 86.221 | 97.975 | 41.664 | - | 41.664 | 25.670 | 15.951 | 34.836 | 58.658 | Continuing | Continuing |
| • MT4: *Mitigate (ACD&P)* | 16.935 | 28.785 | 43.364 | - | 43.364 | 44.601 | 36.558 | 5.309 | 11.643 | Continuing | Continuing |

**Remarks**

**D. Acquisition Strategy**

Advanced System for Protection and Integration Reduction of Encumbrances (ASPIRE)

The ASPIRE Next Generation Respirator efforts will be accomplished by awarding an agreement through the Countering Weapons of Mass Destruction Other Transaction Authority (CWMD OTA) to procure multiple prototypes for further development and evaluation to select a final solution.

Accelerated Antibodies - Enhanced Biological Defense (AA-ENBD)

AA-ENBD, in collaboration with interagency partners at Biomedical Advanced Research and Development Authority (BARDA) & Defense Advanced Research Projects Agency (DARPA), will address multiple high-priority threats by developing antibody solutions and advancing them through Phase 1 clinical trials. Additionally, all necessary studies will be completed to enable advanced development, as desired. AA-ENBD will provide a stockpile of 5-10K doses that will remain on a stability program as a potential rapid response capability for deployment via the Rapid Access to Products in Development (RAPID) program. Furthermore, a commercial manufacturing process will be leveraged and developed that can be rapidly implemented for a larger response if needed. The intention is to work each candidate to the appropriate regulatory level (e.g., through Phase 1) within a codified timeframe (e.g., 2 years) from initiation. These efforts will leverage the Other Transactions Authority (OTA) through the medical OTA consortium.

Biological Containment Isolation System - Enhanced Biological Defense (BCIS-ENBD)

The BCIS-ENBD approach will fund prototype system design and development through the Countering Weapons of Mass Destruction Other Transaction Agreement (CWMD OTA) contract. Prototypes will undergo evaluation and further refinement to optimize performance and minimize total ownership cost.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

Generative Unconstrained Intelligent Drug Engineering - Enhanced Biological Defense (GUIDE-ENBD)

GUIDE experimental and advanced computational tools, to include artificial intelligence and machine learning, are tailored specifically to Warfighter threats and needs through a preemptive approach that broadly addresses a diverse and dynamic threat space. GUIDE's intelligent drug design enables medical countermeasures (MCM) candidates to be developed across a wider aperture of threat space thereby reducing early development time. MCM candidates, particularly in the case of high priority threats, can be advanced preemptively. The GUIDE program offers a revolutionary approach to addressing unanticipated endemic and engineered threats through rapid retargeting and optimization. GUIDE is a collaboration between the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (CBRND) (JPEO-CBRND), Defense Advanced Research Projects Agency (DARPA), and the Department of Energy (DOE). The GUIDE program is utilizing Interagency Agreements (IAA) with the DOE National Labs as well as an Other Transaction Authority (OTA) agreement for high throughput testing and data library requirements.

Medical Countermeasures Platform Technologies (MCMPT)

The goal of the MCMPT is to rapidly counter a broad-spectrum of threat agents using standardized discovery, design, manufacturing, and testing processes to reduce medical countermeasure (MCM) development risks. Efforts will focus on transitioning S&T programs from other DoD agencies, such as the Defense Threat Reduction Agency (DTRA)-Joint Science and Technology Office (JSTO) or Defense Advanced Research Projects Agency (DARPA) and establishing advanced platform technologies within the Department of Defense (DoD)'s Advanced Development Manufacturing (ADM) network and evaluating that capability through nonclinical and clinical testing. A subset of these technologies, such as the DARPA Pandemic Prevention Platform (P3), will be adapted to deliver a rapid response capability to novel and emerging threats. Once established, future programs will be able to leverage these platforms for the development of future MCMs. It is anticipated that these efforts will leverage the Other Transactions Authority (OTA), through the medical OTA consortium, or Army Contracting Command-Edgewood.

Plague Monoclonal Antibodies (PLG MAB)

The Plague Monoclonal Antibodies (PLG MAB) program was initiated under the MCMPT program and continued using the Accelerated Antibodies contracting mechanism Medical CBRN Defense Consortium Other Transaction Agreement (MCDC OTA). The program's Milestone Development Decision (MDD) was approved 26 OCT 2022. The program will remain pre-Milestone B and conduct the necessary non-clinical testing, and large-scale manufacturing needed to conduct a Phase 1 clinical trial. This data will be used to provide the warfighter an interim fielding capability via the Rapid Access to Products in Development program (RAPID).

Portable Patient Transport System - Enhanced Biological Defense (PPTS-ENBD)

The PPTS-ENBD effort will resource prototype system design and development through the Countering Weapons of Mass Destruction Other Transaction Authority (CWMD OTA). Leverage lessons learned from previous efforts to optimize performance and minimize total ownership cost.

Shipboard Isolation System (SIS)

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

The SIS program will utilize the Countering Weapons of Mass Destruction Other Transaction Authority (CWMD OTA) to design, procure, and test iterative prototypes to meet the shipboard isolation requirements. Once a final prototype design is selected and successfully completes testing and user evaluations, a technical data package (TDP) and logistics package will be developed. The program will culminate in the procurement and fielding of systems for ship use that will be stored at fleet concentration areas on both CONUS and OCONUS locations.

Vaccine Acceleration By Modular Progression - Enhanced Biological Defense (VAMP-ENBD)

The Vaccine Acceleration by Modular Progression (VAMP) program is an investment program that leverages lessons learned, industrial leaders, established manufacturing processes, and interagency partners (including Biomedical Advanced Research and Development Authority (BARDA), Defense Innovation Unit (DIU)) to develop prototype vaccine candidates utilizing matured platforms from established commercial manufacturing that target biothreats while utilizing a modular approach to ensure flexibility. These prototype vaccines (including, but not limited to, Messenger Ribonucleic Acid (mRNA) vaccines) will use a tailored acquisition pathway and will create a strategic reserve to counter the biothreats against the Warfighter and shorten the development time when an emergency occurs. Data generated from these efforts may be used to support an interim fielding capability (U.S. Food & Drug Administration (FDA) pre-Emergency Use Authorizations (EUA)/EUA and Expanded Access protocols) that could be used to achieve FDA licensure as appropriate. These efforts will leverage the Other Transactions Authority (OTA) through the Medical CBRN Defense consortium, Broad Agency Announcements, and Commercial Solutions Opening. Data on VAMP products will be captured within Rapid Acquisition of Products in Development (RAPID) defense system to aid in identification of MCMs to counter threats.

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ASPIRE - HW C - Prototypes | MIPR | U.S. Army Contracting Command (ACC-NJ) : Picatinny, NJ | - | 0.000 | | 0.000 | | 1.125 | May 2025 | - | | 1.125 | Continuing | Continuing | 0.000 |
| AA-ENBD - HW C - Development | Various | Various : N/A | - | 53.690 | Dec 2022 | 62.544 | Dec 2023 | 39.072 | Dec 2024 | - | | 39.072 | Continuing | Continuing | 0.000 |
| GUIDE-ENBD - SW S - Development | Various | Various : N/A | - | 50.050 | Dec 2022 | 45.713 | Dec 2023 | 53.045 | Dec 2024 | - | | 53.045 | Continuing | Continuing | 0.000 |
| MCMPT - HW S - Rapid Response | C/CPFF | TBD : N/A | - | 4.282 | Dec 2022 | 4.782 | Dec 2023 | 4.646 | Dec 2024 | - | | 4.646 | Continuing | Continuing | 0.000 |
| MCMPT - HW S - P3/ Nucleic Acid | C/CPFF | TBD : N/A, | - | 5.247 | Dec 2022 | 3.930 | Dec 2023 | 7.172 | Dec 2024 | - | | 7.172 | Continuing | Continuing | 0.000 |
| MCMPT - HW S - Manufacturing | C/CPFF | TBD : N/A | - | 0.000 | | 0.993 | Dec 2023 | 1.385 | Dec 2024 | - | | 1.385 | Continuing | Continuing | 0.000 |
| PLG MAB - HW S - Manufacturing, Non-Clinical and Clinical Development | Various | Various : N/A | - | 11.970 | Mar 2023 | 13.546 | Dec 2023 | 8.676 | Dec 2024 | - | | 8.676 | Continuing | Continuing | 0.000 |
| VAMP-ENBD - HW C - Vaccine - Development | Various | Various : N/A | - | 28.587 | Dec 2022 | 28.254 | Dec 2023 | 36.809 | Dec 2024 | - | | 36.809 | Continuing | Continuing | 0.000 |
| UIPE FoS Footwear - HW S - Footwear Prototype | C/FFP | TBD : N/A | - | 0.000 | | 0.100 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.100 | 0.000 |
| | | **Subtotal** | - | 153.826 | | 159.862 | | 151.930 | | - | | 151.930 | Continuing | Continuing | N/A |

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ASPIRE - ES SB - Engineering Support | MIPR | Various : N/A | - | 0.000 | | 0.000 | | 0.225 | Jan 2025 | - | | 0.225 | Continuing | Continuing | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| BCIS-ENBD - ES S - Concept Demo Closeout Activities | Various | Various : N/A | - | 0.000 | | 0.000 | | 0.300 | Nov 2024 | - | | 0.300 | Continuing | Continuing | 0.000 |
| PPTS-ENBD - ES S - Concept Demo Closeout Activities | Various | Various : N/A | - | 0.000 | | 0.000 | | 0.300 | Nov 2024 | - | | 0.300 | Continuing | Continuing | 0.000 |
| SIS - ES S - Concept Demo Closeout Activities | Various | Various : N/A | - | 0.000 | | 0.000 | | 0.300 | Nov 2024 | - | | 0.300 | Continuing | Continuing | 0.000 |
| VAMP-ENBD - HW C - Direct Program Support | Various | Various : N/A | - | 3.295 | Nov 2022 | 2.745 | Dec 2023 | 3.978 | Dec 2024 | - | | 3.978 | Continuing | Continuing | 0.000 |
| UIPE FoS Footwear - ES S - Logistics/Engineering Support | Various | Various : N/A | - | 0.000 | | 0.358 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.358 | 0.000 |
| BIOPROTO - TD/D S - OTA | MIPR | U.S. Army Contracting Command (ACC-NJ) : Picatinny, NJ | - | 2.130 | Oct 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 2.130 | 0.000 |
| | | **Subtotal** | - | 5.425 | | 3.103 | | 5.103 | | - | | 5.103 | Continuing | Continuing | N/A |

**Test and Evaluation ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| UIPE FoS Footwear - OTHT S - Infrastructure | MIPR | TBD : N/A | - | 0.000 | | 0.282 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.282 | 0.000 |
| UIPE FoS Footwear - OTHT S - Swatch Testing (new/worn) | TBD | TBD : N/A | - | 0.000 | | 0.500 | Apr 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.500 | 0.000 |
| UIPE FoS Footwear - OTHT S - Early User Testing | TBD | TBD : N/A | - | 0.000 | | 1.000 | Jun 2024 | 0.000 | | - | | 0.000 | 0.000 | 1.000 | 0.000 |
| | | **Subtotal** | - | 0.000 | | 1.782 | | 0.000 | | - | | 0.000 | 0.000 | 1.782 | N/A |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

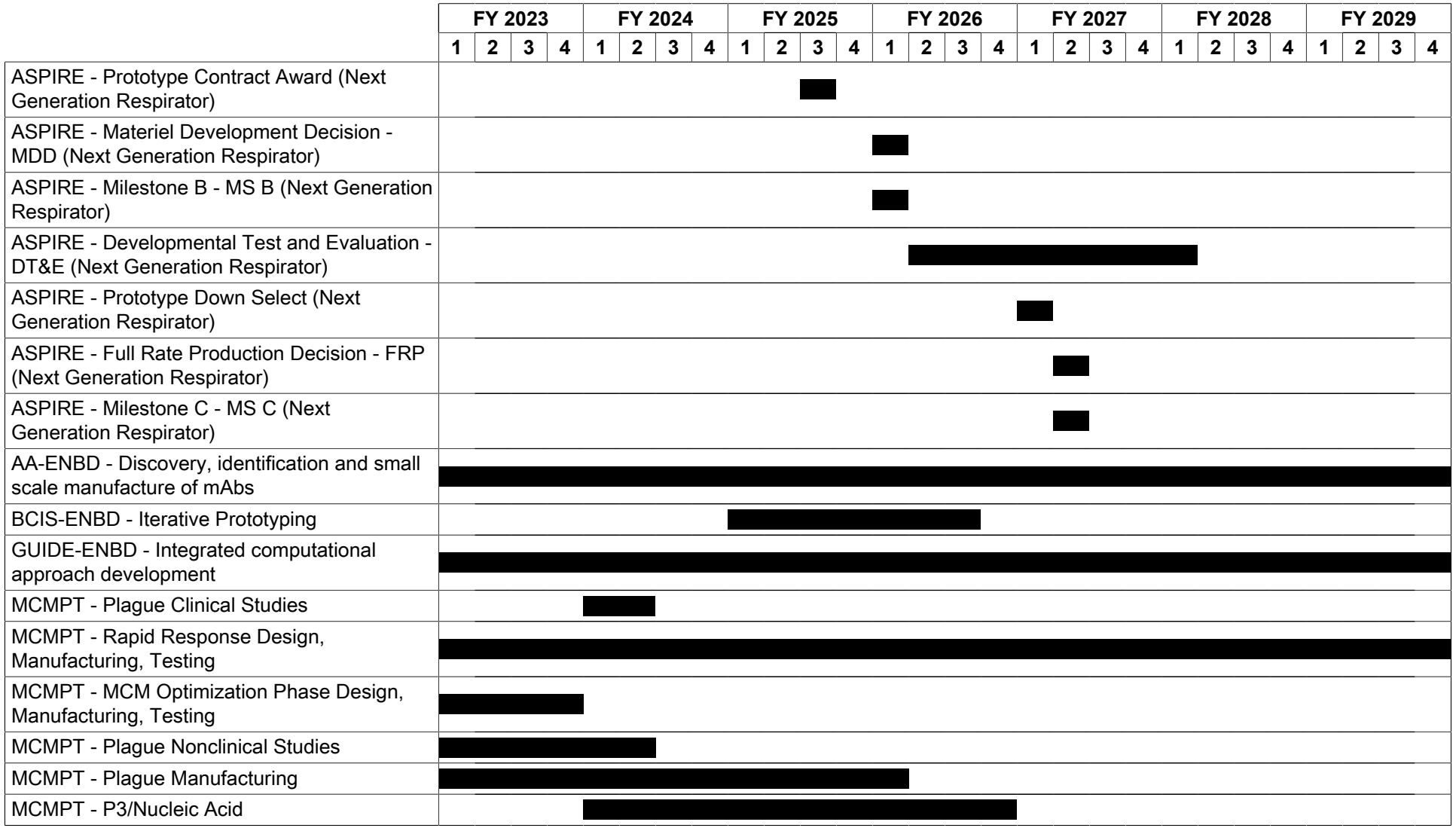
**Management Services ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ASPIRE - PM/MS SB - Program Management Support | MIPR | Various : N/A | - | 0.000 | | 0.000 | | 0.150 | Jan 2025 | - | | 0.150 | Continuing | Continuing | 0.000 |
| AA-ENBD - PM/MS S - Program Management | Various | Various : N/A | - | 4.123 | Dec 2022 | 5.120 | Dec 2023 | 3.198 | Dec 2024 | - | | 3.198 | Continuing | Continuing | 0.000 |
| GUIDE-ENBD - PM/MS S - Program Management | Various | Various : N/A | - | 3.844 | Dec 2022 | 3.920 | Dec 2023 | 5.246 | Dec 2024 | - | | 5.246 | Continuing | Continuing | 0.000 |
| MCMPT - PM/MS S - PM Support | Various | JPL CBRND Enabling Biotechnologies, JPEO-CBRND : Fort Detrick, MD | - | 0.826 | Dec 2022 | 0.771 | Dec 2023 | 1.007 | Dec 2024 | - | | 1.007 | Continuing | Continuing | 0.000 |
| PLG MAB - PM/MS S - Program Management | Various | Various : N/A | - | 0.845 | Dec 2022 | 1.154 | Dec 2023 | 0.674 | Dec 2024 | - | | 0.674 | Continuing | Continuing | 0.000 |
| VAMP-ENBD - PM/MS S - Management Support | Various | Various : N/A | - | 1.899 | Oct 2022 | 3.300 | Dec 2023 | 4.882 | Dec 2024 | - | | 4.882 | Continuing | Continuing | 0.000 |
| UIPE FoS Footwear - PM/MS S - Management Services | Various | Various : N/A | - | 0.000 | | 0.146 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.146 | 0.000 |
| | | **Subtotal** | - | 11.537 | | 14.411 | | 15.157 | | - | | 15.157 | Continuing | Continuing | N/A |

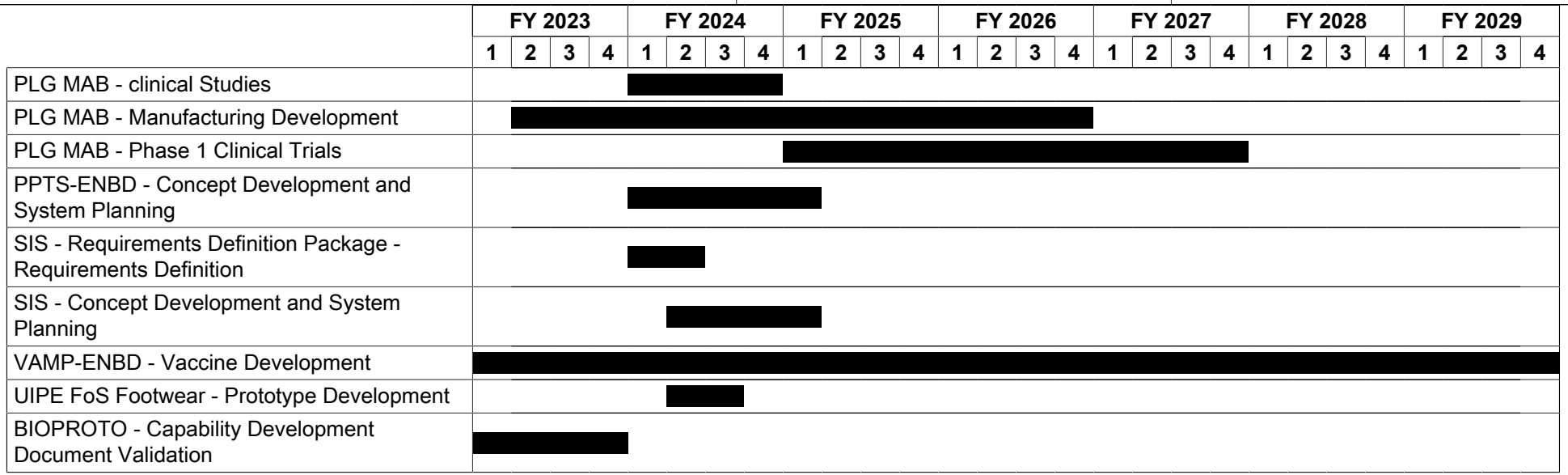
| | Prior Years | FY 2023 | | FY 2024 | | FY 2025 Base | | FY 2025 OCO | | FY 2025 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Project Cost Totals** | - | 170.788 | | 179.158 | | 172.190 | | - | | 172.190 | Continuing | Continuing | N/A |

**Remarks**

| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |



| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |



| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

## Schedule Details

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| ASPIRE - Prototype Contract Award (Next Generation Respirator) | 3 | 2025 | 3 | 2025 |
| ASPIRE - Materiel Development Decision - MDD (Next Generation Respirator) | 1 | 2026 | 1 | 2026 |
| ASPIRE - Milestone B - MS B (Next Generation Respirator) | 1 | 2026 | 1 | 2026 |
| ASPIRE - Developmental Test and Evaluation - DT&E (Next Generation Respirator) | 2 | 2026 | 1 | 2028 |
| ASPIRE - Prototype Down Select (Next Generation Respirator) | 1 | 2027 | 1 | 2027 |
| ASPIRE - Full Rate Production Decision - FRP (Next Generation Respirator) | 2 | 2027 | 2 | 2027 |
| ASPIRE - Milestone C - MS C (Next Generation Respirator) | 2 | 2027 | 2 | 2027 |
| AA-ENBD - Discovery, identification and small scale manufacture of mAbs | 1 | 2023 | 4 | 2029 |
| BCIS-ENBD - Iterative Prototyping | 1 | 2025 | 3 | 2026 |
| GUIDE-ENBD - Integrated computational approach development | 1 | 2023 | 4 | 2029 |
| MCMPT - Plague Clinical Studies | 1 | 2024 | 2 | 2024 |
| MCMPT - Rapid Response Design, Manufacturing, Testing | 1 | 2023 | 4 | 2029 |
| MCMPT - MCM Optimization Phase Design, Manufacturing, Testing | 1 | 2023 | 4 | 2023 |
| MCMPT - Plague Nonclinical Studies | 1 | 2023 | 2 | 2024 |
| MCMPT - Plague Manufacturing | 1 | 2023 | 1 | 2026 |
| MCMPT - P3/Nucleic Acid | 1 | 2024 | 4 | 2026 |
| PLG MAB - clinical Studies | 1 | 2024 | 4 | 2024 |
| PLG MAB - Manufacturing Development | 2 | 2023 | 4 | 2026 |
| PLG MAB - Phase 1 Clinical Trials | 1 | 2025 | 4 | 2027 |
| PPTS-ENBD - Concept Development and System Planning | 1 | 2024 | 1 | 2025 |
| SIS - Requirements Definition Package - Requirements Definition | 1 | 2024 | 2 | 2024 |
| SIS - Concept Development and System Planning | 2 | 2024 | 1 | 2025 |

| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>PT4 / *Protect (ACD&P)* |

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| VAMP-ENBD - Vaccine Development | 1 | 2023 | 4 | 2029 |
| UIPE FoS Footwear - Prototype Development | 2 | 2024 | 3 | 2024 |
| BIOPROTO - Capability Development Document Validation | 1 | 2023 | 4 | 2023 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 4 | R-1 Program Element (Number/Name)<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | Project (Number/Name)<br>MT4 / *Mitigate (ACD&P)* | |

| COST ($ in Millions) | Prior Years | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MT4: *Mitigate (ACD&P)* | - | 16.935 | 28.785 | 43.364 | 0.000 | 43.364 | 44.601 | 36.558 | 5.309 | 11.643 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

**A. Mission Description and Budget Item Justification**

The Mitigate Advanced Component Development and Prototypes (ACD&P) Project provides the Joint Force the ability to conduct decontamination and medical actions that enable the quick restoration of combat power; maintain/recover essential functions that are free from the effects of Chemical Biological Radiological and Nuclear (CBRN) hazards; and facilitate the return to pre-incident operational capability as soon as possible.

Efforts included in this Project are:

(1) Autonomous Decontamination System (ADS)
(2) Agent-Directed Therapeutics (AD TX)
(3) Antiviral Oral Therapeutic (AVO TX)
(4) Botulinum Toxin Therapeutic (BOT TX)
(5) Consolidated Nerve Agent Treatment System (CNATS)
(6) Medical Decontamination Personnel Skin (MED DECON PS)
(7) Reactivating Nerve Agent Treatment System (RNATS)
(8) Tactical Contamination Mitigation System (TCMS)
(9) Biological Warfare Defense Medical Countermeasures Prototype (BIOPROTO)
(10) Discovery of Medical countermeasures Against New and Emerging threats (DOMANE)
(11) Service Equipment Decontamination System (SEDS)

The Autonomous Decontamination System (ADS) is a new start program in FY24 and provides a semi-autonomous supported capability that relies on precision detection capabilities, modernized decontaminants, and robotics to allow a chemical, biological, radiological and nuclear (CBRN) decontamination squad to provide platoon level thorough decontamination on critical mission equipment. In FY25, ADS will complete prototype assessment(s) for robotic/automated technologies that are applicable to contamination mapping and decontamination operations. Additionally, the program will prepare documentation in support of the Milestone A/Technology Maturity and Risk Reduction Phase (Simplified Acquisition Management Plan (SAMP), Life Cycle Sustainment Plan (LCSP), Test and Evaluation Master Plan (TEMP)) and conduct Systems Requirements Review (SRR).

The FY25 new start Agent-Directed Therapeutics (AD TX) will go after multiple virus families to develop and deliver Food and Drug Administration (FDA) approved broad-spectrum antiviral therapeutics drugs against highly contagious emerging threats to the warfighter. Initial drug products will be developed targeting viral hemorrhagic diseases of the Arenavirus and Paramyxovirus viral families. Developed agent directed broad spectrum antivirals therapeutics will be employed after

suspected or confirmed exposure to known or potential threat agents to include natural occurring outbreaks providing a rapid treatment response to the warfighter. In FY25, funding initiates the Natural History Study (NHS) and procurement of long lead items.

The Antiviral Oral Therapeutics (AVO TX) is a new start program in FY24 and will provide the Joint Force the ability to recover from exposure to biological hazards. Efforts include development of Food and Drug Administration (FDA) approved Medical Countermeasure (MCM) to protect the lives and maintain the battle readiness of the warfighter. In FY25, AVO TX funding supports Natural History Study (NHS) and procurement of long lead Items.

The Botulinum Toxin Therapeutic (BOT TX) is a new start program in FY24 and will develop and deliver a U.S. Food and Drug Administration (FDA) approved treatment for the warfighter to treat respiratory depression caused by botulinum intoxication. This intravenous injectable treatment will be developed by reformulating an oral drug product already approved by the FDA. FY25 funding will continue Natural History Study (NHS) and initiate Dose Determination.

The Consolidated Nerve Agent Treatment System (CNATS) is a new start program in FY24 and will deliver an FDA-approved autoinjector that combines anticholinergics, atropine and scopolamine, and a new improved oxime. The proposed oxime will have efficacy against emerging threats including Fourth Generation Agents (FGAs). Combining nerve agent treatments into fewer autoinjectors will reduce basic load for service members and increase the survivability for the warfighter in the United States European Command (EUCOM) and United States Indo-Pacific Command (INDOPACOM) arenas. In FY25, the program will release a solicitation and select a performer and initiate device development.

Medical Decontamination Personnel Skin (MED DECON PS) is a new start in FY25, and will provide a dry/powder personnel decontamination capability to lessen the effects of chemical warfare nerve agents on the skin. MED DECON PS will provide a broad spectrum chemical skin decontamination capability with low logistics footprint (e.g., shelf life and storage conditions) and reduced sustainment costs in comparison to the currently fielded skin decontaminant Reactive Skin Decontamination Lotion (RSDL). In FY25, MED DECON PS will initiate advanced development of the dry powder decontamination technology.

The Reactivator Nerve Agent Treatment System (RNATS) is a new start program in FY24 and will provide the services an FDA-approved improved oxime to address emerging chemical threats and fourth generation agents (FGAs). The program will field a vial formulation as an additional capability and increase the survivability for the warfighter in the United States European Command (EUCOM) and United States Indo-Pacific Command (INDOPACOM) arenas. In FY25, the program will develop and validate the API manufacturing procedures, assays to evaluate the API, and assays to evaluate non-clinical samples, and initiate non-clinical studies.

The Tactical Contamination Mitigation System (TCMS) will address gaps related to the decontamination of critical equipment and vehicles and reduce the time and logistics associated with decontamination. TCMS will limit the spread and mitigate the effects of Chemical, Biological, and Radiological (CBR) contamination to allow warfighters to continue their mission for an extended period of time in a high threat, CBR contaminated environment. The effort will mitigate risk to personnel by limiting the potential spread of CBR contamination and eliminate the need for subsequent decontamination to mitigate contamination on military equipment. TCMS, when combined with weathering, may reduce Mission Oriented Protective Posture (MOPP) level requirements. In FY25, TCMS will complete iterative prototype testing, Test and Evaluation Master Plan (TEMP), Simplified Acquisition Management Plan (SAMP), and Capability Development Document (CDD) in support of Milestone B.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

The Biological Warfare Defense Prototype (BIOPROTO) supports early-phase clinical development and supporting non-clinical safety, tolerability and toxicity data for candidate vaccines and therapeutic drugs prior to transition to System Development & Demonstration. This work provides safe and effective medical defense against validated biological threat agents and emerging infectious disease biothreats including bacteria, toxins, and viruses. This work also involves the evaluation of Food and Drug Administration (FDA) approved therapeutics for operational use, as well as generation of novel drug products and formulations, to enhance level of protection and/or operational utility for the warfighter. This effort reduces programmatic risk of failure in the advanced development phase.

The Discovery of Medical Countermeasures Against New and Emerging threats (DOMANE) supports prototype development of emerging technology platforms and technologies to identify medical countermeasures (MCMs), MCM targets, and disease origin and toxicity using the combination of Artificial Intelligence/Machine Learning, organs-on-a-chip, high-throughput screening as well as novel imaging platforms. Additionally, MT4 supports early-phase clinical development of prophylaxis treatments and therapeutic drugs through the use of adaptive clinical trials to provide safe and effective medical defense against validated biological threat agents and emerging infectious disease biothreats including bacteria, toxins, and viruses. This effort reduces programmatic risk of failure in the advanced development phase by developing validated prototypes and generating clinical and supporting non-clinical safety, tolerability and toxicity data for candidate prophylaxis treatments and therapeutic drugs prior to transition to System Development & Demonstration.

The Service Equipment Decontamination System (SEDS) program consists of two efforts, Joint SEDS and Special Operations Forces (SOF) Critical Equipment Decontamination (CEDS), which will develop a capability for use by the warfighter during decontamination operations that will provide a quantifiable reduction in the number of personnel experiencing adverse health effects by reducing contamination on equipment, individual combat equipment, and sensitive platform interiors (SEDS). This capability is needed to reduce logistical burdens in order to increase tactical agility and sustain a resilient force posture and align with the National Defense Strategy (NDS). SEDS and CEDS will provide contamination mitigation capabilities for critical equipment exposed to chemical and biological contamination and achieve efficacy levels that allow unprotected post-decontamination exposures for long periods with less than negligible severity effects. FY23 is last year of BA4 funding, program is transitioning to Engineering & Manufacturing Development (EMD).

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Title:*** 1) ADS - Prototype Development | - | 1.500 | 2.975 |
| ***Description:*** Development of Robotic Decontamination Systems<br><br>***FY 2024 Plans:***<br>Begin prototype development, conduct alternative systems review.<br><br>***FY 2025 Plans:***<br>Complete prototype assessment(s) for robotic/automated technologies that are applicable to contamination mapping and decontamination operations. Prepare documentation in support of the MS A/Technology Maturity and Risk Reduction Phase (Simplified Acquisition Management Plan (SAMP), life cycle sustainment plan (LCSP), Test and Evaluation Master Plan (TEMP)) and conduct Systems Requirements Review (SRR).<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:*** | | | |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Increase supports programmatic activities to achieve Milestone A. | | | |
| ***Title:*** 2) AD TX<br>***Description:*** Nonclinical<br>***FY 2025 Plans:***<br>Produce Active Pharmaceutical Ingredients (API) for drug product scale up (Arenavirus) to support execution of the Phase 2 clinical trial. Natural History Study (NHS) and procurement of long lead items (Paramyxovirus).<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program/project is new start effort in FY 2025. | - | - | 7.898 |
| ***Title:*** 3) AVO TX<br>***Description:*** Advanced drug development<br>***FY 2024 Plans:***<br>Initiate Natural History Study (NHS).<br>***FY 2025 Plans:***<br>Continue Natural History Study and initiate efficacy and dose ranging studies, with procurement of long lead items.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase supports programmatic activities including FDA engagements to achieve Milestone B. | - | 3.740 | 7.307 |
| ***Title:*** 4) BOT TX<br>***Description:*** Nonclinical Studies<br>***FY 2024 Plans:***<br>Initiate non-clinical study for Dose Determination following FDA animal rule guidance.<br>***FY 2025 Plans:***<br>Continue Natural History Study (NHS) and Dose Determination following FDA animal rule guidance.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to cost efficiencies realized in the Natural History Study (NHS). | - | 2.847 | 2.196 |
| ***Title:*** 5) BOT TX<br>***Description:*** Manufacturing | - | 5.000 | 9.428 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***FY 2024 Plans:***<br>Initiate scale-up manufacturing for intermuscular injection product.<br>***FY 2025 Plans:***<br>Continue scale-up manufacturing for intravenous injection product.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Increase due to additional testing requirements and technical readiness associated with the pilot efficacy study. | | | |
| ***Title:*** 6) CNATS<br>***Description:*** Acquisition and Prototype Manufacturing<br>***FY 2024 Plans:***<br>Assess feasibility of drug combination.<br>***FY 2025 Plans:***<br>Initiate activities to support Milestone A and B. Initiate prototype design and formulation/process development. Continue Affordability Analysis to support the development of Program goals. Continue Technology Readiness Assessment for potential candidate materiel solutions.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>CNATS Acquisition Activities funding consolidated with the CNATS Acquisition and Prototype Manufacturing efforts. Overall CNATS decrease due to technical maturation activities. | - | 1.500 | 3.690 |
| ***Title:*** 7) CNATS<br>***Description:*** Acquisition Activities<br>***FY 2024 Plans:***<br>Initiate activities to support the Milestone Development Decision (MDD) and Milestone B.<br>1. Perform Market Research and develop AoA study guidance and plan as required.<br>2. Perform Affordability Analysis to support the development of Program goals.<br>3. Perform Technology Readiness Assessment for potential candidate materiel solutions.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>CNATS Acquisition Activities consolidated under one CNATS funding line to support Milestone B activities. | - | 2.388 | - |
| ***Title:*** 8) MED DECON PS | - | - | 1.751 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Description:*** Initiate Business Case Analysis (BCA)<br><br>***FY 2025 Plans:***<br>Initiate and complete Business Case Analysis (BCA) of the dry/powder technology to determine if it lowers the lifecycle sustainment risk of Reactive Skin Decontamination Lotion (RSDL).<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program/project is new start effort in FY 2025. | | | |
| ***Title:*** 9) RNATS<br><br>***Description:*** FDA approved oxime in a vial<br><br>***FY 2024 Plans:***<br>Initiate development of broad spectrum oxime for FDA approval. Initiate Natural History Studies for alternative large animal model development. Initiate API procurement and compounding development.<br><br>***FY 2025 Plans:***<br>Initiate drug development, initiate manufacturing and systems engineering.<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program activities begin their apex in FY25, which accounts for the increased costs, bulk of activities continue into FY27. | - | 5.270 | 7.119 |
| ***Title:*** 10) TCMS<br><br>***Description:*** Milestone (MS) A support and Prototype Development<br><br>***FY 2024 Plans:***<br>Continue iterative prototype testing and complete technical reviews and documentation in support of the Milestone (MS) B/ Engineering Manufacturing & Development (EMD) Phase.<br><br>***FY 2025 Plans:***<br>Complete iterative prototype testing, Test and Evaluation Master Plan (TEMP), Simplified Acquisition Management Plan (SAMP), and Capability Development Document (CDD) in support of Milestone B. Upon Milestone B approval, will conduct a Critical Design Review (CDR) and initiate Developmental and Operation testing (DT/OT).<br><br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>FY25 funding decrease due to the program's transition to Engineering and Manufacturing Development (EMD) phase in Q2FY25. | 4.177 | 6.540 | 1.000 |
| ***Title:*** 11) BIOPROTO | 2.444 | - | - |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***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 Food and Drug Administration (FDA)-approved therapeutics are limited or lacking. Program is ending FY24 to align to higher priority activities | | | |
| ***Title:*** 12) DOMANE<br>***Description:*** Prototype Development and Early-Phase Clinical Development | 0.890 | - | - |
| ***Title:*** 13) SEDS<br>***Description:*** Milestone (MS) B support and Prototype Development: Technology Maturation and Risk Reduction (TMRR) Phased Activities to support MS-B and Prototype Development | 9.424 | - | - |
| **Accomplishments/Planned Programs Subtotals** | 16.935 | 28.785 | 43.364 |

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

| Line Item | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • PT4: *Protect (ACD&P)* | 170.788 | 179.158 | 172.190 | - | 172.190 | 154.024 | 131.577 | 137.660 | 120.758 | Continuing | Continuing |
| • MT3: *Mitigate (ATD)* | 83.766 | 100.791 | 81.920 | - | 81.920 | 90.704 | 84.795 | 86.434 | 86.435 | Continuing | Continuing |
| • MT5: *Mitigate (SDD)* | 66.596 | 88.441 | 65.958 | - | 65.958 | 68.516 | 80.822 | 100.320 | 97.781 | Continuing | Continuing |
| • PHM045: *Botulinum Therapeutic (BOT TX)* | - | - | - | - | - | - | - | - | - | 0.000 | 0.000 |
| • PHM007: *Service Equipment Decontamination System (SEDS)* | - | - | 14.028 | - | 14.028 | 22.531 | 24.920 | 13.050 | 11.258 | Continuing | Continuing |
| • PHM042: *Tactical Contamination Mitigation System (TCMS)* | - | - | - | - | - | - | 4.072 | 5.000 | 5.000 | Continuing | Continuing |

**Remarks**

**D. Acquisition Strategy**

Autonomous Decontamination System (ADS)

The ADS acquisition approach will focus on the integration of hardware and software components to deliver a capability that performs decontamination procedures autonomously. It will use developmental, government off the shelf (GOTS), and commercial off the shelf (COTS) products using a system of systems approach and

prototyping. The program will conduct developmental, operational, and integration testing to understand how an autonomous decontamination system will be employed, operated, and supported considering the current military operational framework.

Agent-Directed Therapeutics (AD TX)

The Agent-Directed Therapeutics (AD TX) mechanisms of action will go after multiple virus families. The acquisition strategy supports the development of broad-spectrum therapeutics against highly contagious bio-warfare threats. The regulatory approach of the program is to pursue development for Food & Drug Administration (FDA) approval and leverage Animal Rule when unethical to conduct human clinical trials. The acquisition strategy is for viral hemorrhagic diseases and Paramyxoviruses viruses that will leverage safety and proof of concept studies from Science and Technology (S&T) partners. AD TX will utilize multiple contracting and management strategies (Broad Agency Announcements, Other Transaction Authority (OTA), Indefinite Delivery Indefinite Quantity (IDIQ) FAR-based contracting to provide accelerated response capability to the warfighter.

Antiviral Oral Therapeutic (AVO TX)

The Antiviral Oral Therapeutic Program (AVO TX) program acquisition strategy supports the development through the Engineering, Manufacturing and Development (EMD) phase for a U.S. Food and Drug Administration (FDA) approved oral broad spectrum antiviral therapeutic for the warfighter. Initial drug product will be developed targeting Eastern Equine Encephalitis Virus (EEEV), with potential for other indications as a broad spectrum oral antiviral. The operational concept is to provide an oral broad-spectrum therapeutic Medical Countermeasures (MCM) to the Joint Force following a “trigger event” relating to a virus exposure (e.g., a credible intelligence report of use or potential use, a positive outcome of an environmental sample analysis, or a clinical specimen diagnostic test). This program will leverage safety and large scale manufacturing from COVID.

Botulinum Toxin Therapeutic (BOT TX)

The Botulinum Toxin Therapeutic (BOT TX) program will transition from the Joint Science and Technology Office for Chemical and Biological Defense (JSTO-CBD) to the Joint Program Executive Office for Chemical, Biological, Radiological, and Nuclear Defense (JPEO-CBRND). The Botulinum Toxin Therapeutic (BOT TX) program acquisition strategy supports the Technology Maturity and Risk Reduction (TMRR) phase for a US Food and Drug Administration (FDA) approved broad spectrum treatment for the Warfighter against respiratory depression caused by botulinum intoxication. Initial drug product will be developed targeting Botulinum Neurotoxin (BoNT) A, with potential for other indications as a broad-spectrum treatment. BOT TX is part of the layered defense against (BoNT) covering treatment that may be combined with additional FDA-regulated Medical Countermeasures (MCMs) to prevent casualties and minimize the impact of BoNT intoxication. This product will produce a continuous intravenous capability that is based on an oral drug already approved for human use by the FDA. This program will leverage manufacturing from the FDA approved oral product.

Consolidated Nerve Agent Treatment System (CNATS)

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

In the CNATS acquisition strategy, a contractor will sponsor and conduct activities to achieve Food and Drug Administration (FDA) approval. CNATS will be leveraging current scopolamine development effort and leveraging improved oximes currently in the development pipeline as well as leveraging and optimizing partnerships for assessment/development of the autoinjector. The government contemplates utilizing an Other Transaction Authority (OTA) agreement. Upon FDA approval, a follow-on procurement contract will acquire quantities of product to meet Full Operational Capability (FOC). Sustainment will be the responsibility of the Defense Logistics Agency Troop Support. Post marketing commitments and requirements are anticipated as a result of the FDA approval and will be the responsibility of the contractor and the government.

Medical Decontamination Personnel Skin (MED DECON PS)

Medical Decontamination Personnel Skin is the recipient advanced development program of record at the Joint Project Manager for Chemical, Biological, Radiological, and Nuclear Medical (JPM CBRN Medical). MED DECON PS will evaluate and develop options to replace or enhance the fielded Reactive Skin Decontamination Lotion (RSDL). MED DECON PS will conduct extensive market surveillance and support an analysis of alternatives for suitable replacement technologies to address affordability and storage limitations of the legacy RSDL product. MED DECON PS will develop a regulatory strategy as the technology is anticipated to require U.S. Food and Drug Administration (FDA) licensure as a medical device, or a combination product.

Reactivating Nerve Agent Treatment System (RNATS)

The Reactivator Nerve Agent Treatment System (RNATS) acquisition strategy will leverage prior investments in prior oxime developments by Canada and the United Kingdom. A contractor shall be responsible for conducting activities associated with drug development to obtain U.S. Food and Drug Administration (FDA) approval via a government Other Transaction Authority (OTA) agreement. The contractor shall sponsor the drug. Subsequent purchases for product sustainment will be made by the Defense Logistics Agency (DLA) Troop Support. Post marketing commitments and requirements are anticipated as a result of the FDA approval and will be the responsibility of the contractor and the government.

Tactical Contamination Mitigation System (TCMS)

The TCMS will utilize the Countering Weapons of Mass Destruction Other Transaction Authority (CWMD OTA) to conduct market research through Requests for Information (RFIs) and a call for White Papers. The OTA vehicle will also be used to request prototypes, which will undergo technology demonstrations and Early Field testing, followed by an analysis to determine the most suitable candidate. Results of Prototyping will inform Milestone B and Request for Proposals (RFPs) followed by developmental and operational testing and Milestone C/Full Rate Production Approval.

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADS - HW S - Prototype Modification | TBD | TBD : N/A | - | 0.000 | | 0.356 | Jan 2024 | 0.786 | Jan 2025 | - | | 0.786 | Continuing | Continuing | 0.000 |
| AD TX - HW GFPP - Product Development | TBD | Various : N/A | - | 0.000 | | 0.000 | | 7.020 | Dec 2024 | - | | 7.020 | Continuing | Continuing | 0.000 |
| BOT TX - HW GFPP - Nonclinical/Manufacturing | Various | Various : N/A | - | 0.000 | | 6.590 | Dec 2023 | 10.971 | Dec 2024 | - | | 10.971 | Continuing | Continuing | 0.000 |
| CNATS - HW C - Acq Activities/ M/S A&B | Various | TBD : N/A | - | 0.000 | | 2.925 | Mar 2024 | 2.974 | Apr 2025 | - | | 2.974 | Continuing | Continuing | 0.000 |
| CNATS - HW SB - Direct Product Support | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.535 | Nov 2023 | 0.321 | Dec 2024 | - | | 0.321 | Continuing | Continuing | 0.000 |
| MED DECON PS - HW C - Business Case Analysis (BCA) | TBD | TBD : N/A | - | 0.000 | | 0.000 | | 1.033 | Dec 2024 | - | | 1.033 | Continuing | Continuing | 0.000 |
| MED DECON PS - HW C - Direct Product | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.000 | | 0.273 | Dec 2024 | - | | 0.273 | Continuing | Continuing | 0.000 |
| MED DECON PS - HW C - Program Mgmt Labor | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.000 | | 0.270 | Dec 2024 | - | | 0.270 | Continuing | Continuing | 0.000 |
| RNATS - HW C - Development | TBD | Various : N/A | - | 0.000 | | 4.208 | Jun 2024 | 5.738 | Dec 2024 | - | | 5.738 | Continuing | Continuing | 0.000 |
| RNATS - HW SB - Direct Product Support | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.482 | Jan 2024 | 0.619 | Dec 2024 | - | | 0.619 | Continuing | Continuing | 0.000 |
| TCMS - HW S - Product Development | C/FFP | TBD : N/A | - | 0.681 | Nov 2022 | 1.800 | Jan 2024 | 0.000 | Jan 2025 | - | | 0.000 | 0.000 | 2.481 | 0.000 |
| SEDS - HW S - Product Development | SS/FFP | TBD : N/A | - | 0.281 | Nov 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.281 | 0.000 |
| SEDS - HW C - CEDS Product Development | C/FFP | Integrated Solutions for Systems (IS4S) : Huntsville, AL | - | 0.442 | Aug 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.442 | 0.000 |
| | | **Subtotal** | - | 1.404 | | 16.896 | | 30.005 | | - | | 30.005 | Continuing | Continuing | N/A |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADS - ES S - Engineering Support | MIPR | TBD : N/A | - | 0.000 | | 0.225 | Nov 2023 | 0.950 | Nov 2024 | - | | 0.950 | Continuing | Continuing | 0.000 |
| TCMS - ES S - Logistics, Engineering and IPT Support | MIPR | Various : N/A | - | 0.833 | Nov 2022 | 0.981 | Nov 2023 | 0.303 | Nov 2024 | - | | 0.303 | Continuing | Continuing | 0.000 |
| BIOPROTO - TD/D S - Clinical/Non-clinical studies for Broad Spectrum antibacterial/ antiviral candidates | MIPR | Aceragen : Cambridge, MA | - | 2.444 | Oct 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 2.444 | 0.000 |
| DOMANE - TD/D S - Hardware/Software | MIPR | Wake Forest University Health Sciences : Winston Salem, NC | - | 0.890 | Oct 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.890 | 0.000 |
| SEDS - ILS S - Logistics, Engineering and IPT Support | MIPR | Various : N/A | - | 1.722 | Nov 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 1.722 | 0.000 |
| SEDS - ES S - CEDS Support | C/CPFF | Various : N/A | - | 0.126 | Mar 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.126 | 0.000 |
| | | **Subtotal** | - | 6.015 | | 1.206 | | 1.253 | | - | | 1.253 | Continuing | Continuing | N/A |

**Test and Evaluation ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADS - DTE S - Prototype System Testing | MIPR | TBD : N/A | - | 0.000 | | 0.827 | Nov 2023 | 0.889 | Nov 2024 | - | | 0.889 | Continuing | Continuing | 0.000 |
| AVO TX - DTE C - Non Clinical Studies | Various | Various : N/A | - | 0.000 | | 2.940 | Dec 2023 | 6.387 | Mar 2025 | - | | 6.387 | Continuing | Continuing | 0.000 |
| TCMS - OTHT S - Prototype T&E IPR Test Planning | MIPR | Various : N/A | - | 2.399 | Jan 2023 | 3.358 | Nov 2023 | 0.598 | Nov 2024 | - | | 0.598 | Continuing | Continuing | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

**Test and Evaluation ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SEDS - OTHT S - T&E IPR Test Planning | MIPR | Various : N/A | - | 4.153 | Nov 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 4.153 | 0.000 |
| SEDS - DTE C - CEDS T&E | C/CPFF | MRIGlobal : Kansas City, MO | - | 1.590 | Nov 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 1.590 | 0.000 |
| | | **Subtotal** | - | 8.142 | | 7.125 | | 7.874 | | - | | 7.874 | Continuing | Continuing | N/A |

**Management Services ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ADS - PM/MS S - Program Management | MIPR | TBD : N/A | - | 0.000 | | 0.092 | Nov 2023 | 0.350 | Nov 2024 | - | | 0.350 | Continuing | Continuing | 0.000 |
| AD TX - PM/MS S - Management Services | TBD | Various : N/A | - | 0.000 | | 0.000 | | 0.878 | Dec 2024 | - | | 0.878 | Continuing | Continuing | 0.000 |
| AVO TX - PM/MS S - Management Support | Various | Various : N/A | - | 0.000 | | 0.800 | Dec 2023 | 0.920 | Dec 2024 | - | | 0.920 | Continuing | Continuing | 0.000 |
| BOT TX - PM/MS C - Management Support | Various | Various : N/A | - | 0.000 | | 1.257 | Dec 2023 | 0.653 | Dec 2024 | - | | 0.653 | Continuing | Continuing | 0.000 |
| CNATS - PM/MS S - Management Services | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.428 | Nov 2023 | 0.395 | Dec 2024 | - | | 0.395 | Continuing | Continuing | 0.000 |
| MED DECON PS - PM/MS S - Management Services | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.000 | | 0.175 | Dec 2024 | - | | 0.175 | Continuing | Continuing | 0.000 |
| RNATS - PM/MS S - Management Support | Various | JPM CBRN Medical, JPEO-CBRND : Fort Detrick, MD | - | 0.000 | | 0.580 | Dec 2023 | 0.762 | Dec 2024 | - | | 0.762 | Continuing | Continuing | 0.000 |
| TCMS - PM/MS S - Program Management Support | Various | Various : N/A | - | 0.264 | Nov 2022 | 0.401 | Jan 2024 | 0.099 | Nov 2024 | - | | 0.099 | Continuing | Continuing | 0.000 |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

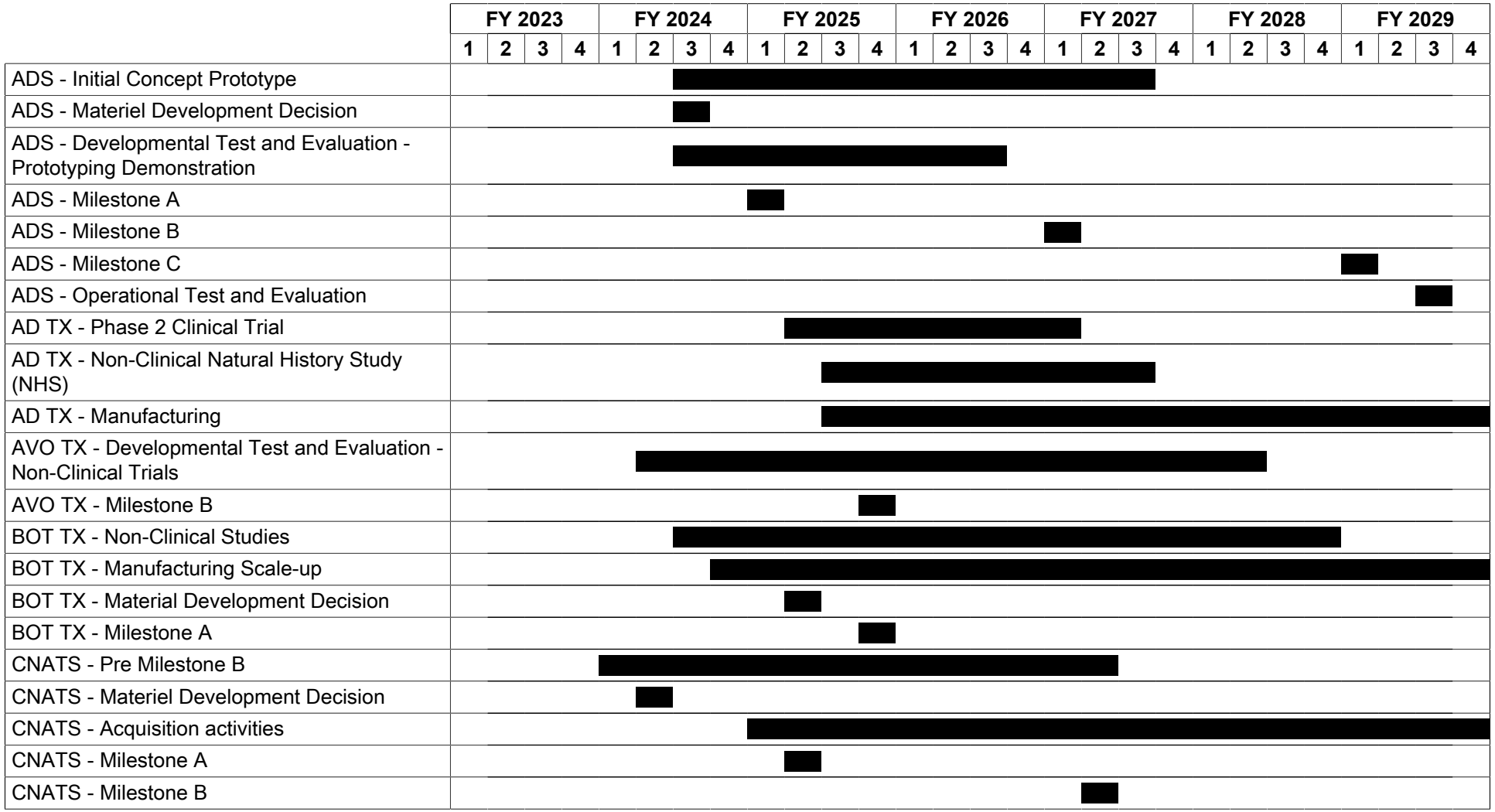
**Management Services ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| SEDS - PM/MS S - Program Management Support | MIPR | Various : N/A | - | 0.859 | Nov 2022 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.859 | 0.000 |
| SEDS - PM/MS C - CEDS Management | C/FFP | Various : N/A | - | 0.251 | Mar 2023 | 0.000 | | 0.000 | | - | | 0.000 | 0.000 | 0.251 | 0.000 |
| | | **Subtotal** | - | 1.374 | | 3.558 | | 4.232 | | - | | 4.232 | Continuing | Continuing | N/A |

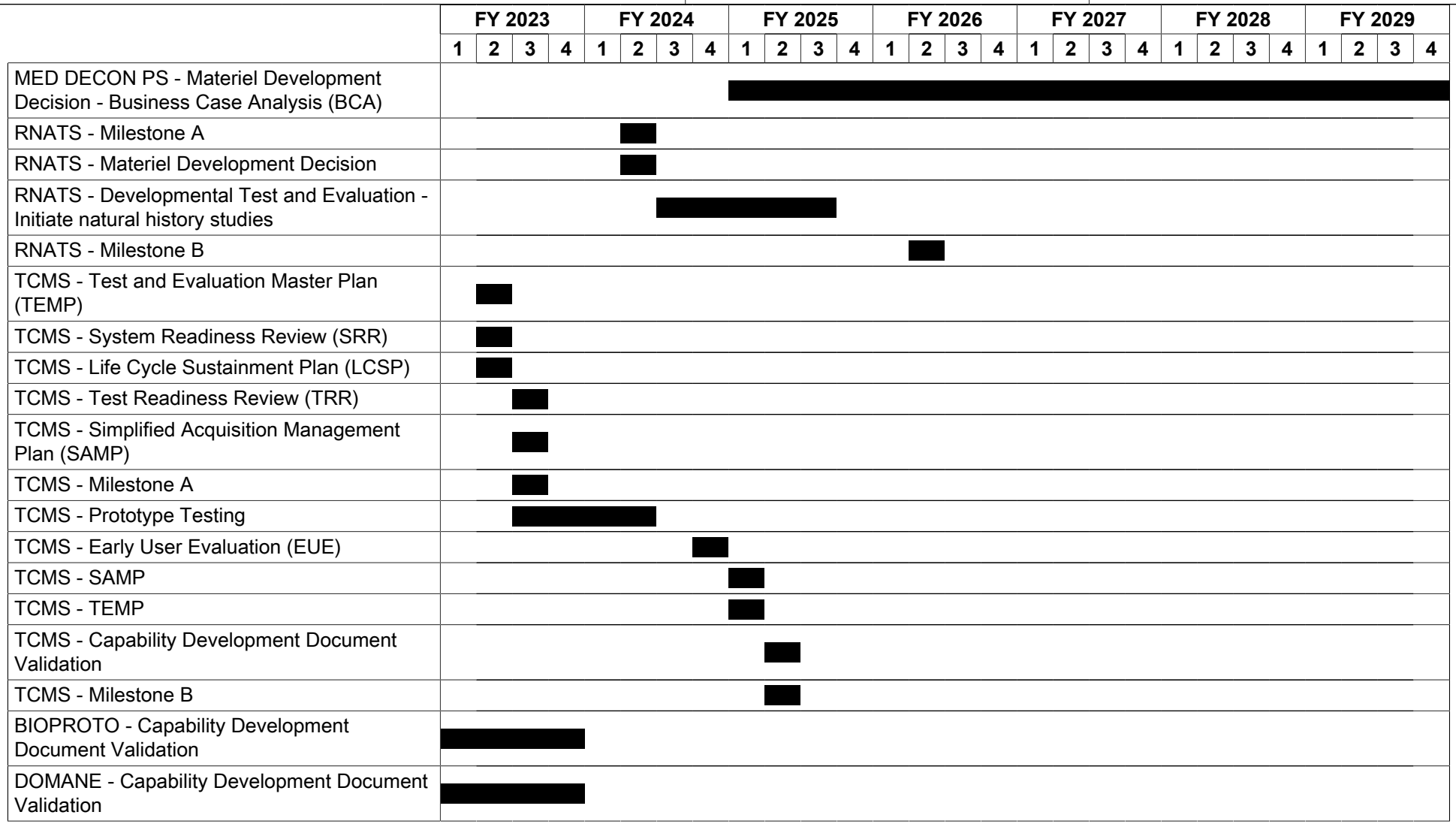
| | Prior Years | FY 2023 | | FY 2024 | | FY 2025 Base | | FY 2025 OCO | | FY 2025 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Project Cost Totals** | - | 16.935 | | 28.785 | | 43.364 | | - | | 43.364 | Continuing | Continuing | N/A |

**Remarks**

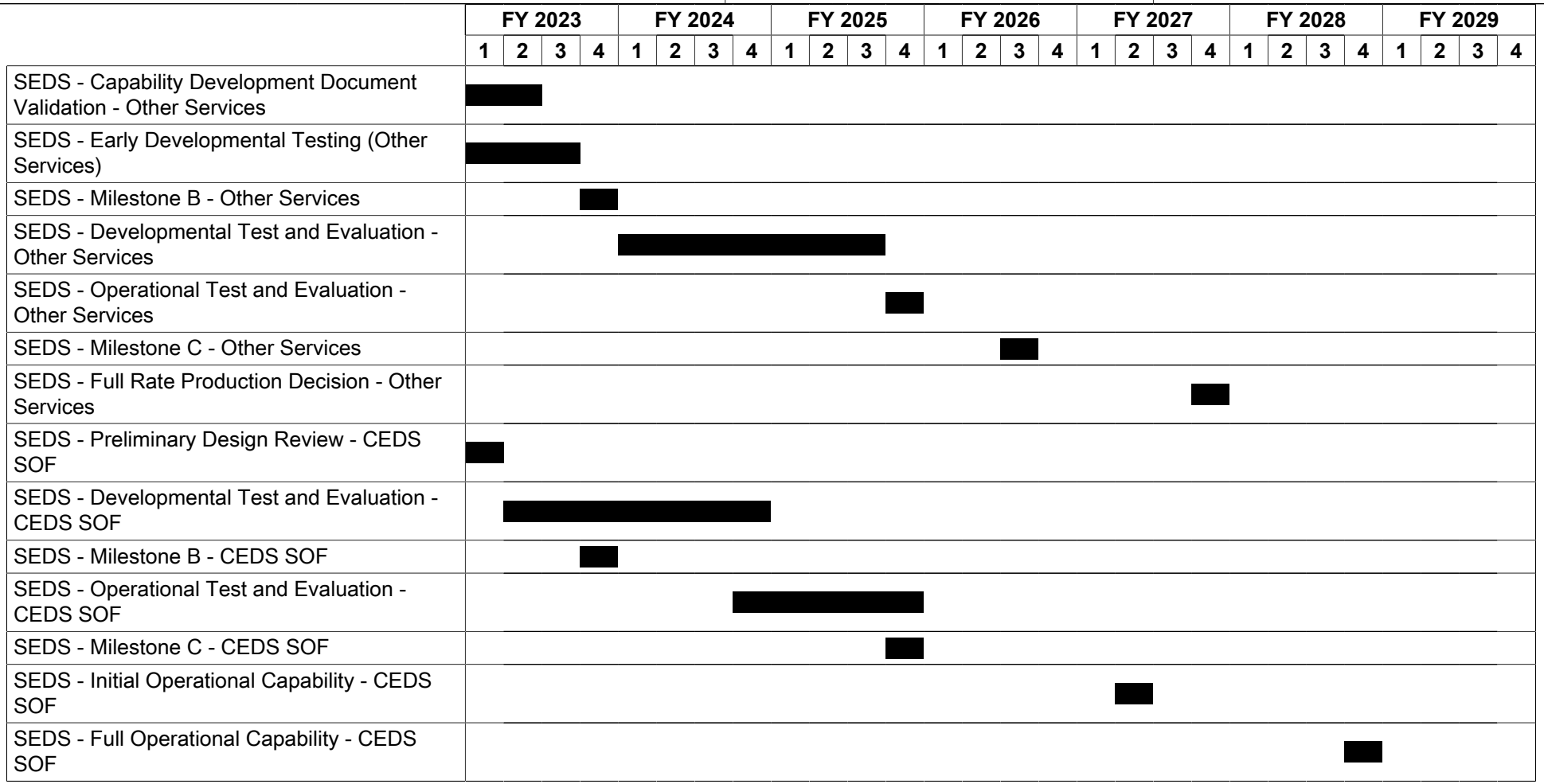
| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |



| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |



| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |



| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

## Schedule Details

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| ADS - Initial Concept Prototype | 3 | 2024 | 3 | 2027 |
| ADS - Materiel Development Decision | 3 | 2024 | 3 | 2024 |
| ADS - Developmental Test and Evaluation - Prototyping Demonstration | 3 | 2024 | 3 | 2026 |
| ADS - Milestone A | 1 | 2025 | 1 | 2025 |
| ADS - Milestone B | 1 | 2027 | 1 | 2027 |
| ADS - Milestone C | 1 | 2029 | 1 | 2029 |
| ADS - Operational Test and Evaluation | 3 | 2029 | 3 | 2029 |
| AD TX - Phase 2 Clinical Trial | 2 | 2025 | 1 | 2027 |
| AD TX - Non-Clinical Natural History Study (NHS) | 3 | 2025 | 3 | 2027 |
| AD TX - Manufacturing | 3 | 2025 | 4 | 2029 |
| AVO TX - Developmental Test and Evaluation - Non-Clinical Trials | 2 | 2024 | 2 | 2028 |
| AVO TX - Milestone B | 4 | 2025 | 4 | 2025 |
| BOT TX - Non-Clinical Studies | 3 | 2024 | 4 | 2028 |
| BOT TX - Manufacturing Scale-up | 4 | 2024 | 1 | 2030 |
| BOT TX - Material Development Decision | 2 | 2025 | 2 | 2025 |
| BOT TX - Milestone A | 4 | 2025 | 4 | 2025 |
| CNATS - Pre Milestone B | 1 | 2024 | 2 | 2027 |
| CNATS - Materiel Development Decision | 2 | 2024 | 2 | 2024 |
| CNATS - Acquisition activities | 1 | 2025 | 4 | 2029 |
| CNATS - Milestone A | 2 | 2025 | 2 | 2025 |
| CNATS - Milestone B | 2 | 2027 | 2 | 2027 |
| MED DECON PS - Materiel Development Decision - Business Case Analysis (BCA) | 1 | 2025 | 4 | 2029 |

| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| RNATS - Milestone A | 2 | 2024 | 2 | 2024 |
| RNATS - Materiel Development Decision | 2 | 2024 | 2 | 2024 |
| RNATS - Developmental Test and Evaluation - Initiate natural history studies | 3 | 2024 | 3 | 2025 |
| RNATS - Milestone B | 2 | 2026 | 2 | 2026 |
| TCMS - Test and Evaluation Master Plan (TEMP) | 2 | 2023 | 2 | 2023 |
| TCMS - System Readiness Review (SRR) | 2 | 2023 | 2 | 2023 |
| TCMS - Life Cycle Sustainment Plan (LCSP) | 2 | 2023 | 2 | 2023 |
| TCMS - Test Readiness Review (TRR) | 3 | 2023 | 3 | 2023 |
| TCMS - Simplified Acquisition Management Plan (SAMP) | 3 | 2023 | 3 | 2023 |
| TCMS - Milestone A | 3 | 2023 | 3 | 2023 |
| TCMS - Prototype Testing | 3 | 2023 | 2 | 2024 |
| TCMS - Early User Evaluation (EUE) | 4 | 2024 | 4 | 2024 |
| TCMS - SAMP | 1 | 2025 | 1 | 2025 |
| TCMS - TEMP | 1 | 2025 | 1 | 2025 |
| TCMS - Capability Development Document Validation | 2 | 2025 | 2 | 2025 |
| TCMS - Milestone B | 2 | 2025 | 2 | 2025 |
| BIOPROTO - Capability Development Document Validation | 1 | 2023 | 4 | 2023 |
| DOMANE - Capability Development Document Validation | 1 | 2023 | 4 | 2023 |
| SEDS - Capability Development Document Validation - Other Services | 1 | 2023 | 2 | 2023 |
| SEDS - Early Developmental Testing (Other Services) | 1 | 2023 | 3 | 2023 |
| SEDS - Milestone B - Other Services | 4 | 2023 | 4 | 2023 |
| SEDS - Developmental Test and Evaluation - Other Services | 1 | 2024 | 3 | 2025 |
| SEDS - Operational Test and Evaluation - Other Services | 4 | 2025 | 4 | 2025 |
| SEDS - Milestone C - Other Services | 3 | 2026 | 3 | 2026 |
| SEDS - Full Rate Production Decision - Other Services | 4 | 2027 | 4 | 2027 |

| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>MT4 / *Mitigate (ACD&P)* |

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| SEDS - Preliminary Design Review - CEDS SOF | 1 | 2023 | 1 | 2023 |
| SEDS - Developmental Test and Evaluation - CEDS SOF | 2 | 2023 | 4 | 2024 |
| SEDS - Milestone B - CEDS SOF | 4 | 2023 | 4 | 2023 |
| SEDS - Operational Test and Evaluation - CEDS SOF | 4 | 2024 | 4 | 2025 |
| SEDS - Milestone C - CEDS SOF | 4 | 2025 | 4 | 2025 |
| SEDS - Initial Operational Capability - CEDS SOF | 2 | 2027 | 2 | 2027 |
| SEDS - Full Operational Capability - CEDS SOF | 4 | 2028 | 4 | 2028 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | | | | | | | | | | Date: March 2024 | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 4 | | | | | R-1 Program Element (Number/Name)<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | | | | Project (Number/Name)<br>EN4 / *Enabling Investments (ACD&P)* | | | |
| **COST ($ in Millions)** | **Prior Years** | **FY 2023** | **FY 2024** | **FY 2025 Base** | **FY 2025 OCO** | **FY 2025 Total** | **FY 2026** | **FY 2027** | **FY 2028** | **FY 2029** | **Cost To Complete** | **Total Cost** |
| EN4: *Enabling Investments (ACD&P)* | - | 6.645 | 47.272 | 35.700 | 0.000 | 35.700 | 23.500 | 17.800 | 25.800 | 20.200 | Continuing | Continuing |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

**A. Mission Description and Budget Item Justification**

The Enabling Investments Advanced Component Development and Prototypes (ACD&P) Project maintains the Department of Defense (DoD) advanced development manufacturing facility to rapidly develop, manufacture, and approve medical countermeasures. Enabling efforts in this area support dedicated infrastructure capabilities, demonstrations, and overarching development support functions as portfolio enablers responding to emerging threats. Priority access to the facility provides an on demand manufacturing capability not only for the DoD but for the entire United States Government enterprise.

Efforts included in this Project are:

(1) Chemical Biological Incident Preparedness and Response - Advanced Development and Manufacturing (CBIPR-ADM)
(2) Chemical Biological Incident Preparedness and Response - Model Development (CBIPR-MODEL)
(3) Medical Countermeasures Manufacturing Optimization (MCM MFRO)

The CBIPR-ADM ensures prioritization to domestic biopharmaceutical manufacturing capacities, capabilities, and infrastructure (e.g. the DoD-ADM Facility and other strategic partners) that are operationally ready to rapidly develop and manufacture medical countermeasures (MCMs) against current and emerging chemical and biological threats including pandemic response. Prioritization is achieved by establishing and enhancing proven biopharmaceutical manufacturing platform technologies and infrastructure at these facilities. Thus, these facilities will have the capability to accelerate development of MCMs at all stages of development, enhance preparedness for existing threats, and rapidly respond to emerging threats as part of a medical integrated layered defense. MCMs that benefit from these efforts include: Vaccines for Viral Agents, Vaccines for Bacterial Agents and Toxins, monoclonal antibodies, antibody fragments and conjugates for therapeutic and prophylactic use across all agent classes. In FY25, CBIPR-ADM transitions to CBIPR-MODEL based on current incident preparedness and response requirements.

The Chemical Biological Incident Preparedness and Response - Model Development (CBIPR-MODEL) effort will seek to purchase nonclinical models and/or purchase future nonclinical models in advance of CBDP program (S&T and Advanced Development) study needs. In FY25, this effort supports the purchase of nonclinical models.

The Medical Countermeasure Manufacturing Optimization (MCM MFRO) postures the DoD to rapidly respond to biological incidents by leveraging partners across Industrial Base, Chemical and Biological Defense Program, and Defense Health Program to reduce time required to onshore materials critical to the rapid production of medical countermeasures. Furthermore, MCM MFRO will increase the use of computational tools and manufacturing controls to optimize development of MCMs for accelerated delivery to the Warfighter, initiate development of starting materials and conduct a process efficiency study. In FY25, MCM MFRO will continue to optimize manufacturing platforms and continue development of critical reagents, and a rapid sourcing database for starting materials and critical reagents.

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| ***Title:*** 1) CBIPR-ADM<br>***Description:*** Establish proven enabling manufacturing technologies at the Department of Defense (DoD) ADM Capability Building.<br>***FY 2024 Plans:***<br>Continue activities to technology-transfer and establish new manufacturing technologies and infrastructure that support the development and manufacturing of medical countermeasures (MCMs) at the DoD-ADM Facility and strategic partners. This approach ensures that the DoD's efforts are not limited to a single facility. New manufacturing technologies can come from any government sources (including JSTO, WRAIR, BARDA, etc. when mature enough for BA4 funding) and/or other external sources and targets of opportunity from industry.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program/project funding transferred to another funding line. Decrease due to funding transition for current incident preparedness and response requirements under CBIPR-MODEL. | 6.645 | 9.172 | - |
| ***Title:*** 2) CBIPR-MODEL<br>***Description:*** Nonclinical Model<br>***FY 2025 Plans:***<br>Initiate contract to support the purchase of nonclinical models at staggered intervals.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Program/project funding transferred from another funding line. Increase from the CBIPR-ADM transfer is due to revised priorities within the CBIPR portfolio to initiate modeling efforts. | - | - | 12.000 |
| ***Title:*** 3) MCM MFRO<br>***Description:*** Biologics Optimization<br>***FY 2024 Plans:***<br>Initiate optimization of computational tools and manufacturing tools to reduce the cost per dose and time to field for medical countermeasures through optimization of cell productivity and control, in order to improve product quality, consistency, and stability.<br>***FY 2025 Plans:*** | - | 27.000 | 19.000 |

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* |

| B. Accomplishments/Planned Programs ($ in Millions) | FY 2023 | FY 2024 | FY 2025 |
|---|---|---|---|
| Continue to develop innovative approaches that span the drug development lifecycle for optimization of the current manufacturing platforms/techniques for the seamless integration into an emergency response system.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to transition to test and evaluation portion. | | | |
| ***Title:*** 4) MCM MFRO<br>***Description:*** Small Molecule Synthesis<br>***FY 2024 Plans:***<br>Initiate development of critical reagents (such as catalysts), repository stockpile of starting materials, and a database for rapid sourcing of starting materials and critical reagents from stockpile or from other sources during a manufacturing surge.<br>***FY 2025 Plans:***<br>Continue development of critical reagents, starting materials, and Active Pharmaceutical Ingredients (API) for stockpile to meet future need for programs.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Decrease due to continuation of Active Pharmaceutical Ingredients (API) development for stockpile. | - | 10.800 | 4.700 |
| ***Title:*** 5) MCM MFRO<br>***Description:*** Process Improvement/Quality<br>***FY 2024 Plans:***<br>Initiate quality release process efficiency study to reduce delays in the manufacturing batch release process.<br>***FY 2024 to FY 2025 Increase/Decrease Statement:***<br>Study concludes in FY24. | - | 0.300 | - |
| **Accomplishments/Planned Programs Subtotals** | 6.645 | 47.272 | 35.700 |

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

| Line Item | FY 2023 | FY 2024 | FY 2025 Base | FY 2025 OCO | FY 2025 Total | FY 2026 | FY 2027 | FY 2028 | FY 2029 | Cost To Complete | Total Cost |
|---|---|---|---|---|---|---|---|---|---|---|---|
| • EN5: *Enabling Investments (SDD)* | 13.120 | 13.835 | 7.985 | - | 7.985 | 13.436 | 11.811 | 18.542 | 16.527 | Continuing | Continuing |

**Remarks**

| Exhibit R-2A, RDT&E Project Justification: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* |

**D. Acquisition Strategy**

Chemical Biological Incident Preparedness and Response Advanced Design Manufacturing (CBIPR-ADM)

CBIPR-ADM establishes new capability-building efforts such as manufacturing platforms using U.S. Food & Drug Administration (FDA) known technologies and infrastructure improvements that will enable new additional medical countermeasure (MCM) product development. This ensures the DOD ADM will continue to be an enduring domestic MCM manufacturing capability that provides the DoD with priority access. CBIPR-ADM will tech transfer and enhance new manufacturing technologies and infrastructure to support the development and manufacturing of MCMs to provide rapid response to known and unknown chemical/biological threats. New manufacturing technologies can come from any government sources (including JSTO, WRAIR, BARDA, etc. when mature enough for BA4 funding) and other external sources and targets of opportunity from industry.

Chemical Biological Incident Preparedness and Response - Model Development (CBIPR-MODEL)

The Chemical Biological Incident Preparedness and Response - Model Development (CBIPR-MODEL) program acquisition strategy will create a process to purchase nonclinical models in advance of the need. It will establish vendor relationships and prevent negative impacts to S&T and Advanced Development program cost and schedules. It will provide a multi-year agreement with the vendor for a regular supply of nonclinical models over the FYDP.

Medical Countermeasures Manufacturing Optimization (MCM MFRO)

MCM MFRO will increase use of computational tools and manufacturing controls to reduce the risk associated with cost per dose and time to field, as well as enhance FDA regulatory compliance. Additionally leverage industrial base partnerships and buy down risks to manufacturing by prioritizing onshoring of key chemicals (active pharmaceutical ingredients (API) and key starting materials (KSMs)) critical to produce DoD-unique enhanced biodefense medical countermeasure needs.

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* | |

**Product Development ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CBIPR-ADM - HW S - Capabilities Establishment | C/CPFF | Resilience Government Services, Inc. : Alachua, Florida | - | 6.337 | Dec 2022 | 8.830 | Dec 2023 | 0.000 | | - | | 0.000 | 0.000 | 15.167 | 0.000 |
| CBIPR-ADM - HW S - Product Management Support | C/CPFF | Various : N/A | - | 0.308 | Dec 2022 | 0.342 | Jan 2024 | 0.000 | | - | | 0.000 | 0.000 | 0.650 | 0.000 |
| MCM MFRO - HW S - Development | Various | TBD : N/A | - | 0.000 | | 35.052 | Dec 2024 | 22.159 | Dec 2024 | - | | 22.159 | Continuing | Continuing | 0.000 |
| | | **Subtotal** | - | 6.645 | | 44.224 | | 22.159 | | - | | 22.159 | Continuing | Continuing | N/A |

**Support ($ in Millions)**

| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| CBIPR-MODEL - TD/D C - Contract award safety/ efficacy models purchase & rearing | TBD | TBD : N/A | - | 0.000 | | 0.000 | | 12.000 | Apr 2025 | - | | 12.000 | Continuing | Continuing | 0.000 |
| | | **Subtotal** | - | 0.000 | | 0.000 | | 12.000 | | - | | 12.000 | Continuing | Continuing | N/A |

**Management Services ($ in Millions)**

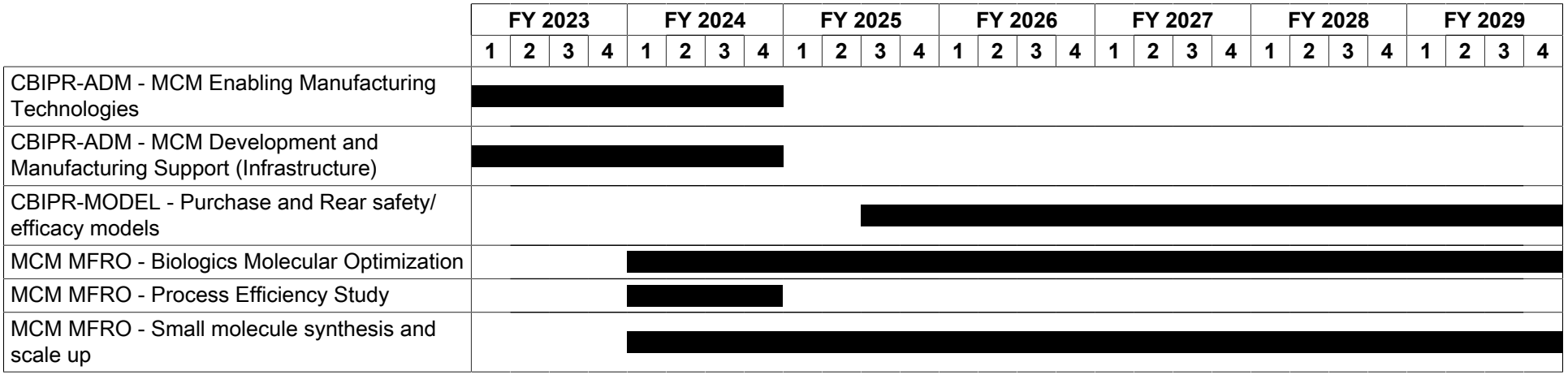
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | FY 2023 Cost | FY 2023 Award Date | FY 2024 Cost | FY 2024 Award Date | FY 2025 Base Cost | FY 2025 Base Award Date | FY 2025 OCO Cost | FY 2025 OCO Award Date | FY 2025 Total Cost | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MCM MFRO - PM/MS S - Program Management | Various | Various : N/A | - | 0.000 | | 3.048 | Dec 2024 | 1.541 | Dec 2024 | - | | 1.541 | Continuing | Continuing | 0.000 |
| | | **Subtotal** | - | 0.000 | | 3.048 | | 1.541 | | - | | 1.541 | Continuing | Continuing | N/A |

| Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Chemical and Biological Defense Program | | | Date: March 2024 |
|---|---|---|---|
| Appropriation/Budget Activity<br>0400 / 4 | R-1 Program Element (Number/Name)<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | Project (Number/Name)<br>EN4 / *Enabling Investments (ACD&P)* | |

| | Prior Years | FY 2023 | | FY 2024 | | FY 2025 Base | | FY 2025 OCO | | FY 2025 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Project Cost Totals** | - | 6.645 | | 47.272 | | 35.700 | | - | | 35.700 | Continuing | Continuing | N/A |

**Remarks**

| Exhibit R-4, RDT&E Schedule Profile: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* |



| Exhibit R-4A, RDT&E Schedule Details: PB 2025 Chemical and Biological Defense Program | | Date: March 2024 |
|---|---|---|
| **Appropriation/Budget Activity**<br>0400 / 4 | **R-1 Program Element (Number/Name)**<br>PE 0603884BP / *Chemical and Biological Defense Program - Dem/Val* | **Project (Number/Name)**<br>EN4 / *Enabling Investments (ACD&P)* |

## Schedule Details

| | Start | | End | |
|---|---|---|---|---|
| **Events** | **Quarter** | **Year** | **Quarter** | **Year** |
| CBIPR-ADM - MCM Enabling Manufacturing Technologies | 1 | 2023 | 4 | 2024 |
| CBIPR-ADM - MCM Development and Manufacturing Support (Infrastructure) | 1 | 2023 | 4 | 2024 |
| CBIPR-MODEL - Purchase and Rear safety/efficacy models | 3 | 2025 | 4 | 2029 |
| MCM MFRO - Biologics Molecular Optimization | 1 | 2024 | 4 | 2029 |
| MCM MFRO - Process Efficiency Study | 1 | 2024 | 4 | 2024 |
| MCM MFRO - Small molecule synthesis and scale up | 1 | 2024 | 4 | 2029 |