Exhibit R-2, RDT&E Budget Item Justification: PB 2025 Defense Advanced Research Projects Agency	Date: March 2024
Appropriation/Budget Activity 0400: *Research, Development, Test & Evaluation, Defense-Wide* / BA 2: *Applied Research*	**R-1 Program Element (Number/Name)** PE 0602115E / *BIOMEDICAL TECHNOLOGY*

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	-	104.150	141.081	169.198	-	169.198	193.238	217.467	229.923	238.108	-	-
BT-01: *BIOMEDICAL TECHNOLOGY*	-	104.150	141.081	169.198	-	169.198	193.238	217.467	229.923	238.108	-	-

A. Mission Description and Budget Item Justification

This Biomedical Technology Program Element (PE) focuses on applied research for medical related technologies that will maintain warfighter health and performance before, during, or after operations. Successful technologies within this Program Element will maintain warfighter health against emerging threats through novel biothreat detection, rapid medical countermeasure identification and development, and distributed production of effective therapeutics. In-theater, warfighter health will be maintained through the development of field-relevant technologies such as reliable and accessible critical medical resources, novel detection and protection capabilities for traumatic brain injury, and rapid, effective triage of battlefield injuries. Technologies are also being developed to provide new capabilities for warfighter recovery from sustained injury including, but not limited to spinal cord injury. Additionally, this PE will improve warfighter readiness by characterizing and assaying physical and cognitive performance to drive data-driven awareness. This PE also supports innovation and robust transition planning in the technology cycle by working with entrepreneurs to increase the likelihood that DARPA-funded technologies take root in the U.S. and provide new capabilities for national defense.

B. Program Change Summary ($ in Millions)	FY 2023	FY 2024	FY 2025 Base	FY 2025 OCO	FY 2025 Total
Previous President's Budget	126.958	141.081	167.205	-	167.205
Current President's Budget	104.150	141.081	169.198	-	169.198
Total Adjustments	-22.808	0.000	1.993	-	1.993
• Congressional General Reductions	0.000	0.000			
• Congressional Directed Reductions	0.000	0.000			
• Congressional Rescissions	0.000	0.000			
• Congressional Adds	0.000	0.000			
• Congressional Directed Transfers	-20.000	0.000			
• Reprogrammings	0.292	0.000			
• SBIR/STTR Transfer	-3.100	0.000			
• TotalOtherAdjustments	-	-	1.993	-	1.993

Change Summary Explanation

FY 2023: Decrease reflects SBIR/STTR transfer and transfer of the 'Prophylactic Medical Countermeasure for Acute Radiation Syndrome' Congressional Add to the Army offset by reprogrammings.

FY 2024: N/A

FY 2025: Increase reflects minor program repricing.

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
Title: Improved Personnel Placement (IPP)	14.163	15.629	8.031
Description: The Improved Personnel Placement (IPP) program aims to improve force lethality and overmatch by identifying candidates for specialized military roles and developing assays to determine physical/cognitive states in order to maximize performance and resilience, while minimizing attrition. IPP will identify and measure biomarkers for unique physical, cognitive, and behavioral traits associated with a broad spectrum of military specialties. The program will link these phenotypic traits and biomarkers to underlying biological gene expression circuits driving performance. This knowledge will help individualize training and provide novel measures of physical/cognitive states for specialized roles, while providing training cadres greater precision for identifying the candidates without bias. Measuring an individual's biological system will ensure that they achieve their maximum potential while facilitating readiness and resilience for the DoD. ***FY 2024 Plans:*** - Generate a preliminary list of published molecular biomarkers indicative of readiness as targets for molecular sensor development. - Begin sensor development for molecular biomarkers associated with physical task readiness. - Initiate evaluation of preliminary models for predicting physical task readiness. - Begin preparations for a demonstration of sensor outputs within a militarily relevant cohort. ***FY 2025 Plans:*** - Complete non-integrated benchtop sensor procedures for molecular biomarkers. - Execute a demonstration of sensor outputs within a militarily relevant cohort. - Begin sensor development for molecular biomarkers associated with cognitive task readiness. - Initiate evaluation of preliminary models for predicting cognitive task readiness. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects reduction of training samples and refinement of models for end of phase demonstration.			
Title: Deployable Medical Countermeasures for Warfighter Readiness	20.133	27.007	25.508
Description: Maintaining robust protection and treatment against infectious disease threats during stabilization operations (e.g., Humanitarian and Disaster Relief [HADR]) requires rapid drug discovery and reducing manufacturing and supply chain burdens. A major limitation of our current response to emerging biological and chemical threats is the lack of immediate availability of ideal medical countermeasures (MCMs) for rapid response, which includes high quality nucleic acid templates for MCM manufacturing. These nucleic acids are also critical for R&D applications ranging from synthetic biology to the testing and development of medical countermeasures. Current DNA production capabilities are limited to less than a handful of U.S.-based manufacturers; it takes weeks to months to produce adequate quality and quantity of DNA at these manufacturing sites and ship them to downstream partners. The Deployable Medical Countermeasures for Warfighter Readiness program aims to develop an on-			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
demand deployable platform to manufacture nucleic acid drugs safely at scale, in short timeframes. The platform will be comprised of a fully contained system capable of selectively manufacturing relevant doses of current Good Manufacturing Process (cGMP) grade nucleic acid therapeutics at or near the point of care. This effort will also develop high quality gene-length DNA for research and development. This on-demand platform will enable countermeasures capable of combating novel threats, allowing a small force to prevent regional outbreaks from becoming global emergencies. ***FY 2024 Plans:*** - Demonstrate an evolved, integrated, and automated process for production and formulation of messenger RNA (mRNA). - Demonstrate integrated automation of mRNA quality analytical methods. - Demonstrate high-throughput de novo enzymatic synthesis of oligonucleotides to support parallel synthesis and assembly of multiple DNA targets. - Develop schematics for integration of modules for nucleic acid synthesis, purification, and analysis into an alpha prototype system for DNA medical countermeasures. - Initiate method development for parallel synthesis and assembly of multiple DNA targets at research and development (R&D) scale. - Conduct cybersecurity resilience of nucleic acid synthesis systems. ***FY 2025 Plans:*** - Demonstrate integrated upstream workflow for parallel synthesis of multiple DNA targets at R&D scale. - Develop functionally integrated alpha prototype system for DNA medical countermeasures, including modules for automated DNA synthesis, purification, and analysis. - Initiate development of alpha prototype system for R&D grade DNA, including modules for parallel DNA synthesis, purification, and analysis. - Demonstrate suitability of product produced through end-to-end automated processes using animal studies, showing identical safety and efficacy compared to traditionally-developed MCMs. - Integrate cybersecurity software and hardware into nucleic acid synthesis systems. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects the completion of DNA synthesis method development and the shift to automation of the methods.			
Title: Bridging the Gap after Spinal Cord Injury ***Description:*** The Bridging the Gap after Spinal Cord Injury program is developing and integrating technologies to heal and restore function associated with spinal cord injuries. This program will significantly advance treatment technologies by developing implantable, adaptive devices to address different stages of spinal cord injury. For early phases of injury, this program will develop technologies for real-time biomarker tracking and delivery of therapies to stabilize or rebuild nerve connections at the injury site.	12.016	17.815	10.155

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
For final phase of injury, the Bridging the Gap after Spinal Cord Injury program will develop and integrate a network of devices deployed across the body to effectively create a synthetic nervous system and "bridge the gap" of the spinal cord injury to restore function and sensory feedback. The Bridging the Gap after Spinal Cord Injury program will dramatically improve the quality of life for wounded warfighters and veterans suffering from spinal cord injuries. ***FY 2024 Plans:*** - Evaluate safety of devices, subsystems, and algorithms in vivo. - Assess efficacy of the injury mitigation systems in vivo. - Initiate experiments to establish implanted device longevity and compatibility with imaging systems. - Improve risk mitigation strategies for the complete system and initiate regulatory body engagement. ***FY 2025 Plans:*** - Initiate efficacy assessment for the early injury mitigation systems in animal models. - Initiate regulatory approval procedures for early injury mitigation systems. - Evaluate efficacy of long-term multi-function restoration in preclinical models. - Submit long-term function recovery systems for regulatory approval. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects completion of initial prototyping and development activities and shift to focus on final testing and transition.			
Title: Distributed Access to Critical Biotherapeutics for Warfighters	10.020	14.520	14.001
Description: The goal of the Distributed Access to Critical Biotherapeutics for Warfighters program is to ensure DoD access to critical medical countermeasures (MCMs) by establishing the foundational technologies needed for fully distributable, on-demand manufacturing of protein-based MCMs and critical reagents. To achieve this, investments will be made in technologies that enable immediate, high-yield synthesis of bioactive protein MCMs. This technology will allow the DoD to rapidly secure access to therapeutic proteins and to enzymes needed for nucleic-acid based MCM synthesis without reliance on complex supply chains or slow development cycles. ***FY 2024 Plans:*** - Identify effectors that increase protein expression yields. - Develop methods to decrease lead-time to protein production in cell free systems. - Demonstrate the addition of modifications to proteins produced in a cell free system.			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
- Conduct a capability demonstration to validate the production of a protein of interest at a yield relevant to operational timeframes. ***FY 2025 Plans:*** - Utilize identified effectors and improved reaction conditions in combination to increase protein expression yields. - Demonstrate initiation of protein production in cell free systems. - Demonstrate the addition of different protein modifications to proteins produced in cell free systems. - Demonstrate production of proteins at relevant yields with correct protein modification added. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects minor program repricing.			
Title: Next-Generation Combat Casualty Care ***Description:*** The Next-Generation Combat Casualty Care program is developing advances in critical efforts to preserve warfighter life and well-being in the battlefields of the future. This research will directly address a leading cause of potentially preventable battlefield casualties by investigating new approaches for developing whole blood substitutes for traumatic injury that can be deployed on the battlefield in far forward settings. Additional potential uses apply to disaster relief, mass casualty events, and stabilization missions. Advances within this program will ensure that the U.S. remains able to care for service members in peer and near-peer conflict by addressing gaps in combat casualty care. ***FY 2024 Plans:*** - Initiate efficacy and safety assessments of therapeutic formulations against hemorrhage using animal models. - Test stability over operationally important temperature ranges using in vitro models. - Provide initial proof-of-concept for scaled-up manufacturing of products. - Prepare for in vivo studies to demonstrate efficacy in complex trauma models. ***FY 2025 Plans:*** - Initiate efficacy and safety assessments of therapeutic formulations against hemorrhage in complex trauma using animal models. - Test stability over operationally important temperature ranges and storage durations exceeding current limits for whole blood using in vitro models. - Provide initial proof-of-concept for scaled-up manufacturing of products with near-cost parity with whole blood. - Prepare for in vivo studies to demonstrate efficacy of stabilized products. ***FY 2024 to FY 2025 Increase/Decrease Statement:***	10.733	14.431	11.167

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
The FY 2025 decrease reflects the completion of initial blood substitute development and the initiation of optimization for complex trauma applications.			
Title: Rapid Battlefield Triage	8.907	20.111	24.173
Description: The Rapid Battlefield Triage program is advancing capabilities to quickly triage warfighters requiring urgent life-saving medical intervention and enable medical resources to provide an appropriate response in current and future battlefields. Today, triage at point-of-injury is limited by subjective assessments, tools that are manually intensive, and physiological signatures with little diagnostic and prognostic value. This program will build on recent biomarker discoveries and innovations in sensing platforms to develop field-portable technologies that support triage in the most challenging operational environments. By optimizing allocation of scarce medical resources and scaling to multiple casualties, these devices will help far-forward units maximize their fighting strength against adversaries that inflict large numbers of casualties and constrain evacuation to advanced medical facilities. ***FY 2024 Plans:*** - Build database of trauma signatures with additional sensor modalities. - Evaluate novel physiological signatures of injury type and severity. - Begin to evaluate approaches for stand-off capture of injury signature by semi-autonomous systems. - Begin to evaluate field-portable triage solutions in challenge competitions. - Conduct initial baseline design, development, and integration of triage solutions in initial integration exercise and large-scale field experimentation. ***FY 2025 Plans:*** - Expand database of trauma signatures with additional sensor modalities. - Continue development of virtual testbed for training and testing of virtual autonomous solutions. - Evaluate approaches for stand-off capture of injury signature by semi-autonomous systems in a virtual environment. - Evaluate field-portable triage solutions. - Evaluate approaches for stand-off capture of injury signature by semi-autonomous systems in a real-world (physical) simulation. - Conduct second baseline design, development, and integration of triage solutions in an integration exercise and second large-scale field experimentation. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 increase reflects shift from analysis and development of a trauma signatures database to large-scale medical triage challenge demonstrations.			
Title: Neurological Assessment and Protection from Brain Injury	9.761	17.609	24.052

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
Description: Building upon technologies discovered under the Restoring Cognitive Capability program (budgeted in PE 0602715E, Project MBT-02), the Neurological Assessment and Protection from Brain Injury program is transforming our current detection and protection strategies against traumatic brain injury (TBI), such as injury from blast exposure. This program is developing prophylactic countermeasures to prevent severe brain injury. Current available tools in far forward operating environments for these injuries are lacking especially those that effectively discriminate between mild- and medium-level trauma. These novel technologies will change the paradigm for treatment of TBI by preventing injury rather than attempting to reverse or repair it. ***FY 2024 Plans:*** - Define the biological events immediately following TBI. - Initiate investigations of approaches to deliver countermeasures. - Identify candidate molecular pathways to develop countermeasures. - Initiate platform design for protective or immediate treatment countermeasures. ***FY 2025 Plans:*** - Link the first biological events to downstream cellular or molecular cascades known to result in cognitive, psychological, or behavioral symptoms of TBI in vivo. - Develop delivery mechanisms that demonstrate high temporal and spatial resolution in small animal models. - Develop first-in-class countermeasures identified with feasibility data supporting mechanism of action and safety. - Evaluate proof-of-principle payload delivery specificity demonstrations. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 increase reflects the completion of druggable target identification and the initiation of development and testing of putative interventions that act on these targets to abridge head trauma-induced pathology.			
Title: Warfighting Performance in Biomedical Technology	-	-	17.231
Description: The DoD ensures force health protection by advancing technologies that sustain the operational reliability and effectiveness of the warfighter. The Warfighting Performance in Biomedical Technology thrust will seek to develop new classes of medical care technologies that prevent and treat injuries that impact warfighter health and performance. This thrust will advance platforms to protect overall force health against the multitude of biothreats and physiological stressors. Technologies that allow autonomous care of patients and greatly improve trauma survivability will also be developed. ***FY 2025 Plans:*** - Evaluate the feasibility of modulating target mechanism(s) for improving emotional health outcome. - Evaluate feasibility of producing heath care sensors capable of autonomous care monitoring in compact form factors.			

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
- Initiate method development for assessing injury care effectiveness and patient monitoring in austere environments. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 increase reflects thrust initiation.			
Title: Controlled Genome Protection ***Description:*** The Controlled Genome Protection program will develop advanced capabilities to control and tune the activity of gene editing technologies. This research leverages previous investment in Genome Protection Technologies-developed laboratory tools to prevent or limit unintended genome editing or engineering. Advances in synthetic and environmental biology have significantly expanded the suite of genome editors and modulators available. Many of the new genome editors have been identified from rare, slow-growing microorganisms with unique metabolic capabilities. New tools, both highly specific as well as broadly acting across these new classes of genome editors, are required to advance our understanding of, our control of, and ultimately our leverage of gene editing technologies across all domains of life. Advances within this program will ensure that the U.S. leads innovation in this widespread, advancing field that poses potential national security threats due to the large-scale democratization of gene editing technologies. ***FY 2025 Plans:*** - Initiate discovery of efficient and broadly acting inhibitors of novel genome editors. - Develop assays for demonstrating inhibition of genome editing in vitro. - Initiate characterization of novel genome editors and their associated inhibitors. - Develop computational tools for identifying inhibitors of genome editors. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 increase reflects program initiation.	-	-	15.440
Title: Novel Delivery Technology for Medical Countermeasures ***Description:*** The DoD requires rapid development of medical countermeasures (MCM) to ensure force health protection and improve our ability to respond to emerging and novel biological threats. Despite recent advancements in development of new MCMs, challenges with delivery limits their current therapeutic potential. While emerging targeted delivery systems such as polymer/lipid nanoparticles and viral vectors have enabled the delivery of large, complex MCM molecules, they are still plagued by lack of widespread availability and effectiveness. Investing in efficient, adaptable delivery technology is crucial for strengthening biosecurity preparedness, and will enable rapid response to the evolving biological threat landscape, whether the threat is natural or manmade. The Novel Delivery Technology for Medical Countermeasures program will develop minimally invasive MCM delivery systems, in which any therapeutic can be quickly formulated and administered to treat or prevent any disease. Developing novel delivery platforms will maintain warfighter health and readiness and enable rapid response to existing and novel biothreats.	-	-	19.440

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
FY 2025 Plans: - Identify candidate delivery chassis and formulation strategies capable of delivering protein or nucleic acid-based countermeasures. - Establish assays/methodologies to monitor expression and availability of countermeasures in vitro and in vivo. - Initiate assessment of delivery chassis in two or more cell types in vitro. - Initiate assessment of delivery chassis for multiple medical countermeasure modalities. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 increase reflects program initiation.			
Title: Neural Signal Interfaces and Applications (NSIA) ***Description:*** As part of their daily duties, many military personnel must handle large volumes of data and interact with complex systems. These tasks could be made less difficult with advanced neurotechnology platforms, but all such devices currently require invasive surgery to implement. The Neural Signal Interfaces and Applications (NSIA) program is developing non-invasive neurotechnologies that are able to interface with the nervous system with high resolution and precision without surgery. NSIA is utilizing recent advances to transduce neural signals through tissue. Current neurotechnology platforms also have clinical applications, and resulting NSIA technologies will likewise provide clinical treatment opportunities for wounded warriors through non-invasive means. ***FY 2024 Plans:*** - Evaluate impact of environmental factors (e.g., location, ambient noise) on system performance. - Assess performance when using multiple brain regions to generate outputs. - Assess performance when sending multiple channels of information to multiple brain regions. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects program completion.	9.716	9.231	-
Title: Forensic Indicators of Threat Exposure (FITE) ***Description:*** The DoD responds to a variety of chemical, biological, and radiological threats around the globe that require protective medical countermeasures to ensure force health protection and warfighter readiness. The Forensic Indicators of Threat Exposure (FITE) program is developing a field-deployable resource to reveal an individual's exposure history to chemical, biological, and radiological threats by characterizing epigenetic signatures in an individual's genome and other biological responses. The program is creating the framework for modular technology capable of performing forensic or diagnostic analysis using epigenetic information to provide high specificity of the type of exposure and when it occurred. This novel capability could	4.251	4.728	-

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C. Accomplishments/Planned Programs ($ in Millions)	FY 2023	FY 2024	FY 2025
serve as a field-forward forensic tool for use by the DoD to assist in Chemical, Biological, Radiological, and Nuclear (CBRN) threat detection and response. ***FY 2024 Plans:*** - Characterize identified biomarkers relevant to DoD need. - Finalize analytical methods to increase sensitivity and specificity for validated human exposure signatures. - Initiate assessment of medical countermeasure delivery modalities and their biological responses. - Initiate assessment of CBRN threats and potential inhibitors. ***FY 2024 to FY 2025 Increase/Decrease Statement:*** The FY 2025 decrease reflects program completion.			
Title: Pandemic Prevention ***Description:*** Military personnel are deployed all over the world for traditional operations that can involve exposure to endemic infectious disease, and are often specifically called upon in response to emerging or re-emerging disease outbreaks with pandemic potential (e.g., Ebola). In both instances, the DoD needs effective countermeasures to protect its deployed forces and maintain warfighter readiness. The Pandemic Prevention program focused on novel methods to accelerate countermeasure discovery, pre-clinical testing, and manufacturing. This program sought to advance and integrate newly developed approaches including bioinformatics assessment of genetic sequencing and nucleic acid-based vaccines and to address technology bottlenecks associated with each stage of medical countermeasure development. Additional research investigated new methods improving the manufacturability, distribution, and delivery of novel therapeutics. Pandemic Prevention enabled an integrated therapeutic development platform that leverages state-of-the-art technologies to prevent disease outbreaks.	4.450	-	-
Accomplishments/Planned Programs Subtotals	104.150	141.081	169.198

D. Other Program Funding Summary ($ in Millions)

N/A

Remarks

E. Acquisition Strategy

N/A