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Exhibit R-2, RDT&E Budget Item Justification: PB 2024 Defense Advanced Research Projects Agency **Date:** March 2023

Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide / BA 2: Applied Research</i>	R-1 Program Element (Number/Name) PE 0602115E / <i>BIOMEDICAL TECHNOLOGY</i>
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
Total Program Element	-	100.475	126.958	141.081	-	141.081	167.205	151.215	151.066	151.066	-	-
BT-01: <i>BIOMEDICAL TECHNOLOGY</i>	-	100.475	126.958	141.081	-	141.081	167.205	151.215	151.066	151.066	-	-

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 or hearing loss. 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)

	<u>FY 2022</u>	<u>FY 2023</u>	<u>FY 2024 Base</u>	<u>FY 2024 OCO</u>	<u>FY 2024 Total</u>
Previous President's Budget	108.698	106.958	120.671	-	120.671
Current President's Budget	100.475	126.958	141.081	-	141.081
Total Adjustments	-8.223	20.000	20.410	-	20.410
• Congressional General Reductions	0.000	0.000			
• Congressional Directed Reductions	0.000	0.000			
• Congressional Rescissions	0.000	0.000			
• Congressional Adds	0.000	20.000			
• Congressional Directed Transfers	0.000	0.000			
• Reprogrammings	-4.684	0.000			
• SBIR/STTR Transfer	-3.539	0.000			
• TotalOtherAdjustments	-	-	20.410	-	20.410

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

Project: BT-01: *BIOMEDICAL TECHNOLOGY*

Congressional Add: *Prophylactic Medical Countermeasure for Acute Radiation Syndrome - Congressional Add*

Congressional Add Subtotals for Project: BT-01

	FY 2022	FY 2023
	-	20.000
	-	20.000

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Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2022	FY 2023
Congressional Add Totals for all Projects	-	20.000

Change Summary Explanation

FY 2022: Decrease reflects SBIR/STTR transfer and reprogrammings.

FY 2023: Increase reflects a Congressional add for Prophylactic Medical Countermeasure for Acute Radiation Syndrome.

FY 2024: Increase reflects initiation of the Correction of Hearing Disorders program as well as the scaling up of efforts in the Rapid Battlefield Triage program.

C. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024
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Title: Neural Signal Interfaces and Applications (NSIA)	16.205	9.716	9.231
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. Resulting technologies will restore function in wounded warriors.			
FY 2023 Plans:			
<ul style="list-style-type: none"> - Conduct studies to collect safety data to enable regulatory approval for clinical system evaluations. - Submit safety evaluation data and documentation to request regulatory approval for further system evaluations. - Conduct refined tests evaluating control of multiple outputs in real-time. - Conduct refined tests evaluating reception of multiple channels of information in real-time. 			
FY 2024 Plans:			
<ul style="list-style-type: none"> - 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 2023 to FY 2024 Increase/Decrease Statement:			
The FY 2024 decrease reflects minor program repricing.			

Title: Forensic Indicators of Threat Exposure (FITE)	14.403	5.251	5.510
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. The program will create the			

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C. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024
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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 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. FITE will also evolve new medical countermeasure (MCM) modalities against chemical and biological threat exposures from bench science to translational science that will advance these modalities into clinical use for the warfighter.

FY 2023 Plans:

- Finalize development of human exposure signatures based on collected samples.
- Assess the ability to distinguish viral from bacterial host-based epigenetic signatures in clinical samples.
- Assess the ability to identify time since exposure or acute infection from collected samples.
- Finalize analytical methods to increase sensitivity and specificity for validated human exposure signatures.
- Perform tests on platform prototype for module integration and workflow implementation in militarily relevant, field forward settings.
- Assess ability of field forward device to analyze epigenetic signatures with optimum sensitivity and specificity from biological samples in the field.

FY 2024 Plans:

- Investigate of targeted delivery of medical countermeasures to specific tissues/cell types.
- Initiate animal model development for testing of new medical countermeasure paradigms.
- Initiate characterization of immune system responses to novel medical countermeasures in animal models.

FY 2023 to FY 2024 Increase/Decrease Statement:

The FY 2024 increase reflects minor program repricing.

Title: Improved Personnel Placement (IPP)

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 study the relationships between genotype and phenotype to 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 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 correct 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 2023 Plans:

	FY 2022	FY 2023	FY 2024
	18.089	14.971	15.629

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2022	FY 2023	FY 2024
<ul style="list-style-type: none"> - Finalize and implement protocols for measuring phenotypic traits and biological features. - Demonstrate validated phenotypic and biological measurements linked to elite performance. - Automate data acquisition and computational tools used to perform in silico analysis of phenotypic and biological features. - Research biomarkers that correlate with high-performing physical/cognitive states and identify tasks to be used as proxies for performance in real-world deployment settings. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Generate a preliminary list of published molecular biomarkers indicative of readiness as targets for molecular sensor development. - Begin development of sensor modalities for molecular biomarkers known to be indicative of readiness and associated with physical tasks. - Initiate evaluation of preliminary models for predicting physical task readiness. - Prepare for a demonstration of sensor outputs and model results within a militarily relevant cohort. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects minor program repricing.</p>				
<p>Title: Deployable Medical Countermeasures for Warfighter Readiness</p> <p>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 US-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-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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Determine the most effective methods for nucleic acid synthesis. - Demonstrate assembly and amplification of nucleic acids using breadboard instrumentation and large-scale amplification. 		21.168	20.133	27.007

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C. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024
<ul style="list-style-type: none"> - Select final formulation characteristics and production process for suitable medical countermeasure safety, efficacy, and stability. - Select full panel of in-line analytical methods. - Initiate development of an integrated alpha prototype instrument for messenger RNA (mRNA) synthesis and purification. - Develop methods for DNA synthesis and assembly with low error rates. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Demonstrate an evolved, integrated and automated process for production and formulation of mRNA. - Demonstrate integrated automation of mRNA quality analytical methods. - Initiate design of mRNA instrument beta prototype. - Develop schematics for integration of modules for nucleic acid synthesis, purification, and analysis into a DNA instrument alpha prototype system. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects expanded investment in technology to develop an integrated instrument for synthesis of DNA molecules for research and development applications as well as medical countermeasures.</p>			
<p>Title: Bridging the Gap after Spinal Cord Injury</p> <p>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 (acute, sub-acute, and chronic). 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. 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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Improve device design and performance features based on results from prototype testing. - Integrate risk mitigation strategies for nervous system access to aid functional restoration. - Initiate studies in an animal model to establish safety of prototype devices and therapies to meet regulatory requirements. - Initiate efficacy experiments in an animal model for the integrated system of systems to mitigate spinal cord injury. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Evaluate safety of devices, subsystems and algorithms in vivo. - Assess efficacy of the injury mitigation systems in vivo. 	10.724	12.016	17.815

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2022	FY 2023	FY 2024
<ul style="list-style-type: none"> - 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. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects the cost of demonstrating the efficacy of spinal cord injury subsystems in multiple large animal models.</p>				
<p>Title: Distributed Access to Critical Biotherapeutics for Warfighters</p> <p>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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Determine the yield of multiple classes of protein-based MCMs or reagents using novel production platforms. - Establish baseline lead time to protein production using the novel production platforms. - Establish a process that adds one type of protein modification to enhance the quality of the protein-based MCM. - Determine ability of novel biological platform to produce therapeutic proteins that are equivalent to state of the art in terms of functionality and quality. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Identify effectors that increase protein expression yields. - Develop novel bioreactors for protein production in a cell free system. - Demonstrate the addition of modifications to proteins produced in a cell free system. - Conduct a capability demonstration to validate the production of a medical countermeasure at a yield relevant to operational timeframes. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects minor program repricing.</p>		8.809	10.020	10.520
<p>Title: Next-Generation Combat Casualty Care</p> <p>Description: The Next-Generation Combat Casualty Care program will develop 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</p>		7.245	10.733	11.260

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C. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024
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<p>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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate efficacy assessments of therapeutic formulations against hemorrhage using in vitro models. - Initiate safety and efficacy demonstrations of stabilized products using in vitro models. - Provide initial proof-of-concept for stabilization and manufacturing approach of products. - Prepare for initial in vivo studies to demonstrate efficacy against hemorrhage. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - 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. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects minor program repricing.</p>			
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<p>Title: Rapid Battlefield Triage</p> <p>Description: The Rapid Battlefield Triage program will advance 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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate development of trauma database to support injury signature development and validation. - Begin to investigate novel physiological signatures of injury type and severity. - Begin to develop algorithms to clean and process sensor data. - Correlate physiological signatures of injury and severity with sensor outputs. 	-	8.907	20.111
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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2022	FY 2023	FY 2024
<ul style="list-style-type: none"> - Develop experimental models to test sensor technologies. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Expand 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. <p>FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects initiating stand-off capture of physiological data and processing to identify injury signatures in real world simulations.</p>				
<p>Title: Neurological Assessment and Protection from Brain Injury*</p> <p>Description: * Formerly Neuroprotection from Brain Injury</p> <p>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 will transform our current detection and protection strategies against traumatic brain injury (TBI), such as injury from blast exposure. This program will develop multi-sensory fieldable TBI assessment tools and 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.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Establish study designs, testing infrastructure, and standards compatible with FDA regulatory guidance for blast models and countermeasure development. - Evaluate biological events immediately following TBI. - Identify candidate biological events that can be targeted for developing protective or immediate treatment countermeasures. <p>FY 2024 Plans:</p> <ul style="list-style-type: none"> - Investigate approaches to deliver countermeasures with high temporal, and spatial precision. - Identify candidate molecular pathways to develop countermeasures. - Link the first biological events to downstream cellular or molecular cascades known to result in cognitive, psychological, or behavioral symptoms of TBI in vivo. 		-	9.761	15.609

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C. Accomplishments/Planned Programs (\$ in Millions)		FY 2022	FY 2023	FY 2024
- Initiate platform design for TBI assessment tools and protective or immediate treatment countermeasures.				
FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects scaling up of research activities to initiate assessment of countermeasure platform development.				
Title: Correction of Hearing Disorders Description: Hearing loss, ringing in the ears, and other hearing disorders are complex conditions that affect millions of service members and veterans. The Correction of Hearing Disorders program will create a new class of devices and therapies for hearing disorders. These novel treatments will be developed as a platform technology--integrated, modular, reliable, and adaptable to a patient's particular condition. Research in this area will improve function for service members and veterans with hearing disorders. FY 2024 Plans: - Evaluate models of hearing information processing that will guide development of treatments. - Evaluate novel biocompatible nanomaterials and tissue engineering approaches to image and restore auditory function. - Assess efficacy of electronic and biological systems approaches to restore processing of auditory information in the inner ear. - Initiate development of plans for modular, integrated auditory function restoration. FY 2023 to FY 2024 Increase/Decrease Statement: The FY 2024 increase reflects program initiation.		-	-	8.389
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 is focusing on novel methods to accelerate countermeasure discovery, pre-clinical testing, and manufacturing. This program seeks 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 will investigate new methods improving the manufacturability, distribution, and delivery of novel therapeutics. Pandemic Prevention will enable an integrated therapeutic development platform that leverages state-of-the-art technologies to prevent disease outbreaks. FY 2023 Plans: - Investigate novel mRNA formulations for increased stability of the formulated mRNA product. - Initiate pre-clinical studies to facilitate a Phase I clinical study of an antibody product that binds and neutralizes more than one target.		3.832	5.450	-

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C. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024
- Complete clinical monitoring of patients in a Phase I gene-encoded antibody clinical safety study.			
<i>FY 2023 to FY 2024 Increase/Decrease Statement:</i> The FY 2024 decrease reflects program completion.			
Accomplishments/Planned Programs Subtotals	100.475	106.958	141.081

	FY 2022	FY 2023
<i>Congressional Add:</i> Prophylactic Medical Countermeasure for Acute Radiation Syndrome - Congressional Add	-	20.000
<i>FY 2023 Plans:</i> - Initiate research for prophylactic medical countermeasure for acute radiation syndrome.		
Congressional Adds Subtotals	-	20.000

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

N/A

Remarks

E. Acquisition Strategy

N/A