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Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 3: Advanced Technology Development (ATD)</i>	R-1 Program Element (Number/Name) PE 0603115A / <i>Medical Development</i>
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
Total Program Element	-	26.711	26.508	-	-	-	0.000	0.000	0.000	0.000	0.000	53.219
EB3: <i>HIV Medical Development</i>	-	26.711	26.508	-	-	-	-	-	-	-	0.000	53.219

A. Mission Description and Budget Item Justification

This Program Element (PE) funds the Military Human Immunodeficiency Virus (HIV) Research Program and the following medical research efforts: Walter Reed Army Institute of Research (WRAIR) Vaccine Production research, Underbody Blast (UBB) research, and Deployed Warfighter Protection. Funding also supports the Medical Operational Data System (MODS), Pharmacovigilance Defense Application System (PVDAS), Mobile HealthCare Environment (MHCE), and the Civilian Authorized Salaries and Other Operational Requirements programs.

The Military HIV Program supports the research and development to develop candidate HIV vaccines, to assess safety and effectiveness in human subjects and to protect military personnel from risks associated with HIV infection.

The WRAIR Vaccine Production Facility research Project supports the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with Food and Drug Administration (FDA) regulations.

The UBB Testing medical research Project provides funds to establish a scientific and statistical basis for evaluating skeletal injuries to vehicle occupants during ground vehicle UBB events. Areas of interest to the Secretary of Defense are medical research that provides an understanding of the human response and tolerance limits and injury mechanisms needed to accurately predict skeletal injuries to ground combat vehicle occupants caused by UBB events. This enhanced understanding will support the establishment of an improved capability to conduct Title 10 Live Fire Test and Evaluation and to make acquisition decisions.

The Deployed Warfighter Protection program Armed Forces Pest Management Board provides for the development of new or improved protection of military personnel from insects and tick vectors of disease pathogens.

The MODS, PPVDAS, and MHCE identify, explore and demonstrate key technologies to overcome medical and military unique technology barriers.

The Civilian Authorized Salaries and other operational requirements provide funding for authorized civilian workforce performing medical research, development, acquisition management and oversight that support the medical research, development, test, and evaluation (RDTE) programs at the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland.

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B. Program Change Summary (\$ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	26.711	26.521	0.000	-	0.000
Current President's Budget	26.711	26.508	0.000	-	0.000
Total Adjustments	0.000	-0.013	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• FFRDC Transfer	-	-0.013	-	-	-

Change Summary Explanation

Fiscal Year 2023 (FY23) funding increase reflects the fact that the FY22 President's Budget request did not include out-year funding.

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Appropriation/Budget Activity 2040 / 3					R-1 Program Element (Number/Name) PE 0603115A / <i>Medical Development</i>				Project (Number/Name) EB3 / <i>HIV Medical Development</i>			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
EB3: <i>HIV Medical Development</i>	-	26.711	26.508	-	-	-	-	-	-	-	0.000	53.219
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

The Military Human Immunodeficiency Virus (HIV) Research Program develops vaccine candidates, to assess their safety and effectiveness in human subjects, and to protect military personnel from risks associated with HIV infection. All HIV technology development is conducted in compliance with United States Food and Drug Administration (FDA) regulations. This program is jointly managed through an Interagency Agreement between the United States Army Medical Research and Development Command (USAMRDC) and the National Institute of Allergy and Infectious Diseases. The cited work is also consistent with the Assistant Secretary of Defense, Research and Engineering Science and Technology focus areas.

The Walter Reed Army Institute of Research (WRAIR) Vaccine Pilot Bioproduction Facility (PBF) is the Department of Defense (DOD) only facility capable of producing good manufacturing practices (GMP) quality biologic products for use in early phase clinical trials. The mission of the WRAIR PBF is to support the development and licensure of vaccines and relevant biologics critical to the global health of our Warfighters serving domestically or abroad in compliance with United States FDA regulations. This project supports vaccine development efforts of strategic importance to the DoD, including Service medical research and development programs, those of other DoD organization such as the Defense Threat Reduction Agency and the Defense Advanced Research Projects Agency, and pandemic bio preparedness for emerging infectious disease threats in the Global Health Security Agenda.

The Underbody Blast (UBB) Testing medical research project will provide new data on the biomechanics of human skeletal response that occurs in an attack on a ground combat vehicle, it will provide better protection to mounted warriors from the effects of underbody blast caused by landmines or improvised explosive devices (IEDs). The data will provide a biomedical basis for the development of a Warrior-representative blast test manikin (the Warrior Injury Assessment Manikin or WIAMan project) and the required biomedically-valid injury criteria that can be used in Title 10 Live Fire Test and Evaluation (LFT&E) to characterize dynamic events, the risk of injury to mounted warriors, and to support acquisition decisions. The data produced by this project will be used to satisfy a critical need for a scientifically valid capability for analyzing the risk of injury caused by UBB.

The Deployed Warfighter Protection project, the Armed Forces Pest Management Board (AFPMB), plans to develop new or improved protection for ground forces from disease-carrying insects. The focus of this program is to develop new or improved systems for controlling insects that transmit malaria, dengue, chikungunya and other emerging infectious diseases under austere, remote, and combat conditions; understand the physiology of insecticidal activity to develop new compounds with greater specific activity and/or higher user acceptability; examine existing area repellents for efficacy and develop new spatially effective repellent systems useful in military situations; develop new methods or formulations for treating cloth to prevent vector biting; and expand the number of active ingredients and formulations of public health pest pesticides, products and application technologies available for safe, and effective applications. The AFPMB partners with the President's Malaria Initiative and the World Health Organization Global Malaria Program to lead development of new tools for insect-borne disease prevention.

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The Medical Operational Data System (MODS) deploys modernized data visualization capabilities to enhance Army Unit and Individual Medical Readiness Reporting. MODS provides Army leadership with a responsive and reliable human resource and readiness information management data system for all categories of military and civilian medical and support personnel. MODS provide Tri-Service support through applications such as Electronic Profile, Behavioral Health, and Medical Education.

The Pharmacovigilance Defense Application System (PVDAS) provides military providers Defense Patient Safety reports from the FDA after a drug's release to market. The program identifies, explores, and demonstrates key information technologies to overcome medical and military unique technology barriers.

The Mobile HealthCare Environment (MHCE) is the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device. The program identifies, explores, and demonstrates key information technologies to overcome medical and military unique technology barriers.

The Civilian Authorized Salaries and Other Operational requirements provide funding for authorized civilian workforce performing medical research, development, acquisition management and oversight that support the medical research, development, test, and evaluation (RDTE) programs at the United States Army Medical Research and Development Command (USAMRDC), Fort Detrick, Maryland.

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

	FY 2021	FY 2022	FY 2023
<p>Title: HIV Medical Development</p> <p>Description: The Military HIV Research Program aims to mature candidate HIV vaccines, to validate their safety and effectiveness in human subjects, and to protect the military personnel from risks associated with HIV infection. These activities also include development of monoclonal antibody candidates to address HIV risk to the blood supply in large scale combat operations This project determines one or more prevention countermeasure candidates that are optimized through pre-clinical down-selection studies in large animal models and conducts human clinical trials in Africa, Asia and the United States to test for safety and immunogenicity (ability to invoke an immune response), and contributes to early proof of concept efficacy testing.</p> <p>FY 2022 Plans: Military Health Research Program will complete a human trial evaluating multi-dose vaccine regimens with the optimized dose of the Army's lead adjuvant, determining a lead protein boost vaccine candidate for further development; determine whether rapid administration of vaccines can elicit stronger antibody responses; determine which formulations of the leading Army adjuvant are the best for safety, immune responses and manufacturing; demonstrate Good Manufacturing Practice manufacture of next generation subtype B mosaic vaccine candidates, informed by results from trials in large animal models.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.</p>	7.909	7.833	-
<p>Title: WRAIR Vaccine Production Facility Research</p>	8.189	8.107	-

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Description: The WRAIR Vaccine Pilot Bioproduction Facility (PBF) will focus on advanced technology development and transition through production of early phase (1/2a) clinical materials from varied platforms, such as live virus, conjugates, recombinant proteins, monoclonal antibodies, Ribonucleic Acid (RNA) and deoxyribonucleic acid (DNA) approaches that: (a) expand collaborative partnerships for product development that meet DoD requirements; (b) open active intramural-based discovery efforts of new products for development; and (c) initiate and extend strategic partnerships with external collaborators (Government and industry) to develop/co-develop potential new biologic approaches to pandemic disease preparedness.</p> <p>FY 2022 Plans: The WRAIR Pilot Bioproduction Facility is a support function for novel S&T programs from across MRDC and the DoD to advance the development of vaccine products into early phase (1/2a) clinical trials. Following full operational capability establishment in FY21 the PBF will focus on fostering partnerships with both internal and external stakeholders to continue vaccine and biologic production efforts to support transfer of 6.1-6.3 budget activities for DoD and external stakeholders. These efforts will align to the technology maturation and risk reduction of medical countermeasures for through early phase (1/2a) clinical trials to assess safety and effectiveness of candidate vaccines to support the warfighter.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.</p>			
<p>Title: Underbody Blast Testing</p> <p>Description: The UBB Testing will provide an understanding of the biomechanics of skeletal injuries that occur in a combat vehicle UBB event involving a landmine or improvised explosive device (IED), and the biomedical basis for the development of a Warrior-representative blast test manikin and associated biomedically-validated injury criteria that can be used to characterize dynamic events and injury risks for Live Fire Test and Evaluation (LFT&E) crew survivability assessments and vehicle development efforts to better protect Warriors from UBB threats.</p>	1.274	-	-
<p>Title: Deployed Warfighter Protection</p> <p>Description: The Deployed Warfighter Protection program will mature new or improved tools to protect deployed forces from disease-carrying insects and ticks.</p> <p>FY 2022 Plans: The Deployed Warfighter Protection program continues early translational research for the development of novel tools that protect deployed forces from biting ticks, mosquitoes and other insects which transmit lethal and force degrading diseases. The Armed Forces Pest Management Board (AFPMB) continues to inform the development of performance requirements and necessary test</p>	6.347	6.303	-

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>and evaluation plans to determine a candidate product's capabilities and limitations. Novel vector control capabilities (including RNAi insecticides targeting specific vector species) and personal bite protection tools (including new uniform fabric technologies and area repellents) will be developed for further testing in operationally relevant environments.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.</p>				
<p>Title: Medical Operational Data System</p> <p>Description: The Medical Operational Data System is the Army's authoritative data source for Individual Medical Readiness (IMR) reporting, and supports Army Global Medical Force Readiness (GMFR) to include the Army Surgeon General Title X responsibilities to recruit, retain, pay and train the Army Medical Force.</p> <p>FY 2022 Plans: MODS will complete the Engineering Process needed for required modifications to the MODS Medical Assembly Mobilization Planning Data Platform to support the Army's evolving business/operational requirements in support of Medical Readiness of the Force.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.</p>		1.868	1.909	-
<p>Title: Pharmacovigilance Defense Application System</p> <p>Description: The PVDAS provides military providers Defense Patient Safety reports from the FDA after a drug's release to market.</p> <p>FY 2022 Plans: Pharmacovigilance Defense Application System will demonstrate modifications to directly access to military healthcare databases, thus eliminating the need for its own data warehouse, to give the application access to the most up-to-date information while also increasing capability and capacity to conduct drug studies and analyses. The results will optimize drug-use safety and improve prescribing practices in the Military Healthcare System (MHS) at reduced total cost of ownership (TCO).</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		0.224	0.304	-

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.				
<p>Title: Mobile Health Care Environment</p> <p>Description: The Mobile HealthCare Environment matures and demonstrates technologies to support the capability of secure, bidirectional messaging and data exchange between patients, providers and clinics using any electronic device.</p> <p>FY 2022 Plans: Will continue device and data integration with backend records databases. Demand in these areas requires extensive requirements analysis, programming, and validation of secure chat, video and file sharing capabilities within the platform expansion completed for data integration.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0603115DHA, Project Code 373H.</p>		0.238	0.331	-
<p>Title: Civilian Authorized Salaries and Other Operational Requirements</p> <p>Description: Funding is provided to the USAMRDC for Medical Research Development Acquisition (RDA) Management and Oversight to include the payroll of civilians as well as nominal operating expense</p> <p>FY 2022 Plans: Will fund civilian salaries and associated expenses (supplies, equipment, travel, etc.) at USAMRDC. Funding also provided regulatory, clinical monitoring and data support for the Special Immunization Program as necessary. This program will provide non-licensed vaccines under FDA oversight to personnel at risk of exposure to selected infectious diseases.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding and mission realigned as part of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0606105DHA, Project Code 376B.</p>		0.662	0.753	-
<p>Title: SBIR/STTR Tax</p> <p>FY 2022 Plans: SBIR/STTR tax.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	0.968	-

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Funding transferred in accordance with Title 15 USC ?638.			
Accomplishments/Planned Programs Subtotals	26.711	26.508	-

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

N/A

Remarks

D. Acquisition Strategy

N/A