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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 6: RDT&E Management Support</i>	R-1 Program Element (Number/Name) PE 0606105A / <i>Medical Program-Wide Activities</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	-	18.973	39.041	-	-	-	0.000	0.000	0.000	0.000	0.000	58.014
CD7: <i>Medical Program-Wide Activities</i>	-	18.973	39.041	-	-	-	-	-	-	-	0.000	58.014

A. Mission Description and Budget Item Justification

This Program Element (PE) funds the Continental United States (CONUS) Laboratory Support Clinical Infrastructure and the Outside the Continental United States (OCONUS) Laboratory Infrastructure Support programs. The CONUS and OCONUS laboratory support programs receive funding for research infrastructure management support at select CONUS and OCONUS laboratories and clinical trial sites; work is done in collaboration with Department of Defense Military Treatment Facilities. This program element does not fund research. It funds the infrastructure support staff enabling research scientists to conduct bio-surveillance and early-to-late-stage clinical investigations into biologics, drugs, protectants, device technologies, and knowledge products.

B. Program Change Summary (\$ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	19.164	39.041	0.000	-	0.000
Current President's Budget	18.973	39.041	0.000	-	0.000
Total Adjustments	-0.191	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-0.191	-			
• SBIR/STTR Transfer	-	-			

Change Summary Explanation

FY 2023 funding increase reflects the fact that the FY 2022 President's Budget request did not include out-year funding.

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Appropriation/Budget Activity 2040 / 6					R-1 Program Element (Number/Name) PE 0606105A / Medical Program-Wide Activities				Project (Number/Name) CD7 / Medical Program-Wide Activities			
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
CD7: Medical Program-Wide Activities	-	18.973	39.041	-	-	-	-	-	-	-	0.000	58.014
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Continental United States (CONUS) Laboratory Infrastructure Support funding provides infrastructure and management support for selected laboratories and research sites and enables basic to late stage clinical investigations on medical products as well as collaborative efforts with the Military Health System's (MHS) Military Treatment Facilities (MTFs). MTFs provide access to the patient populations who will benefit the most from the medical products and capabilities being developed. The funds support the retention of technical subject matter expertise, independent of the number of assigned projects. Administration and infrastructure support efforts include resource management, logistics, safety, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel. The infrastructure funds also support Institutional Review Board functions, research technical support, statistical support, grant writing assistance, and other essential functions for maintaining research in MTFs.

The Outside of the Continental United States (OCONUS) Laboratory Infrastructure Support provides management support for research infrastructure at selected overseas laboratories and research sites that conduct bio surveillance and basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, protectants, technologies, and knowledge products to treat/prevent infectious diseases for the purpose of protecting the Warfighter; this is accomplished through collaborative efforts with the respective host nation governments. These sites are the US Army Medical Research Directorate-Kenya (USAMRD-K) in Nairobi, Kenya, the US Army Medical Research Directorate-Georgia (USAMRD-G) in Tbilisi, Georgia, and the US Army Medical Directorate-Armed Forces Research Institute of Medical Sciences (USAMD-AFRIMS) in Bangkok, Thailand. USAMRD-G is the newest laboratory, and provides support in the Caucasus region, similar to that provided by the laboratories in Kenya and Thailand to East Africa and Southeast Asia regions.

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

	FY 2021	FY 2022	FY 2023
Title: Medical Program-Wide Activities	18.973	37.616	-
Description: CONUS Laboratory Infrastructure Support management for research infrastructure at select laboratories and research sites that conduct basic to late-stage clinical research and evaluation of investigational products, such as biologics, drugs, and devices to treat/prevent poly trauma (multiple traumatic injuries), through collaborative efforts with the MHS MTFs.			
OCONUS Laboratory Infrastructure Support management for research infrastructure at selected overseas laboratories and research sites is integral to support the predicting, detecting, preventing, and treating infectious disease threats to the US military, as well as support for surveillance, training, research, and response activities for emerging infectious disease threats that could affect Service members in those regions. Supported OCONUS laboratories are the US Army Medical Directorate-Armed Forces			

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Research Institute of Medical Sciences (AFRIMS) in Bangkok, Thailand; the US Army Research Directorate-Kenya (USAMRD-K) in Nairobi, Kenya, and the US Army Medical Research Directorate-Georgia (USAMRD-G) in Tbilisi, Georgia.</p> <p>FY 2022 Plans: The CONUS Laboratory Support Clinical Infrastructure project will support efforts for military medical research, as well as sustainment of the administration and infrastructure of CONUS medical research laboratories. These efforts will include support staff engaged in multiple clinical investigations and performing critical roles in research subject engagement, development and review of research protocols, and the creation, analysis, and communication of research data. Efforts with the funding will include: support for clinical investigations, submission for external funding applications, sustainment of a Clinical Investigation Committee to review research protocols and provide research support services, solicitation of collaborative research partnerships with non-federal organizations, utilization of funding opportunities database to assist investigators, and identification of ways to improve submission competitiveness.</p> <p>The OCONUS Laboratory Support Clinical Infrastructure project will support sustainment of the administration and infrastructure support for USAMRD-AFRIMS, USAMRD-AFRICA, and USAMRD-GEORGIA laboratories. These laboratories will provide medical research platforms for surveillance, testing, and evaluation of products to inform the development of interventions for military-relevant endemic diseases. Administration and infrastructure will support efforts include resource management, logistics, safety, regulatory affairs, information technology activities, salaries, utilities, maintenance, security, leasing, transportation, shipping, vehicle maintenance and generator fuel.</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).</p> <p>Funding transferred to Program Element 0606105DHA, Project Code 376B.</p>				
<p>Title: SBIR/STTR Tax</p> <p>FY 2022 Plans: SBIR/STTR Tax</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred in accordance with Title 15 USC 7638.</p>		-	1.425	-
Accomplishments/Planned Programs Subtotals		18.973	39.041	-

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C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy N/A		