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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army **Date:** February 2020

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 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
Total Program Element	-	0.000	0.000	19.891	-	19.891	20.289	20.695	21.109	21.523	0.000	103.507
CD7: <i>Medical Program-Wide Activities</i>	-	0.000	0.000	19.891	-	19.891	20.289	20.695	21.109	21.523	0.000	103.507

Note

This is a new start in FY2021.

This Program Element (PE) is a New Start for Fiscal Year 2021 (FY21).

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.

In FY21 programs these programs were transferred from the Defense Health Agency to the United States Army.

B. Program Change Summary (\$ in Millions)	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total
Previous President's Budget	0.000	0.000	0.000	-	0.000
Current President's Budget	0.000	0.000	19.891	-	19.891
Total Adjustments	0.000	0.000	19.891	-	19.891
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	19.891	-	19.891

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<u>Change Summary Explanation</u> FY21 increase a result of funding transferred to the Army from the Defense Health Program (DHP) Research, Development, Testing and Evaluation (RDTE) Program Elements 0606105DHA Projects 401A and 432A.		

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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 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
CD7: Medical Program-Wide Activities	-	0.000	0.000	19.891	-	19.891	20.289	20.695	21.109	21.523	0.000	103.507
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

Note

This Project is a New Start in Fiscal Year 2021 (FY21).

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, enabling basic to late stage clinical investigations on medical products through 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. 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 funds do not support research, but provide the infrastructure support enabling MTF investigators to compete for research, development, test, and evaluation (RDTE) research funds.

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 2019	FY 2020	FY 2021
Title: Medical Program-Wide Activities	-	-	19.891
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,			

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Appropriation/Budget Activity 2040 / 6	R-1 Program Element (Number/Name) PE 0606105A / <i>Medical Program-Wide Activities</i>	Project (Number/Name) CD7 / <i>Medical Program-Wide Activities</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2019	FY 2020	FY 2021
<p>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 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 2021 Plans: The CONUS Laboratory Support Clinical Infrastructure project will support efforts for military medical research. 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 MTF 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 USAMD-AFRIMS, USAMRD-K, and USAMRD-G 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, information technology activities, salaries, utilities, maintenance, transportation, shipping, vehicle maintenance and generator fuel.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding transferred from the Defense Health Program (DHP) RDTE Program Elements 0606105DHA Projects 401A and 432A, starting in FY21.</p>				
Accomplishments/Planned Programs Subtotals		-	-	19.891
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
N/A				