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Exhibit R-2, RDT&E Budget Item Justification: PB 2025 Army **Date:** March 2024

Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 5: System Development & Demonstration (SDD)</i>	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>
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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	-	25.035	6.496	7.143	-	7.143	6.566	6.633	6.707	6.772	0.000	65.352
832: <i>Field Medical Systems Engineering Development</i>	-	25.035	6.496	7.143	-	7.143	6.566	6.633	6.707	6.772	0.000	65.352

A. Mission Description and Budget Item Justification

This Program Element (PE) funds advanced development of medical materiel within the System Demonstration and Low Rate Initial Production portions of the acquisition life cycle using Budget Activity 6.5 (System Development and Demonstration) funding. It supports products successfully developed in the Systems Integration portion of the Systems Development and Demonstration phases through completion of the Milestone C Decision Review. Commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use, when available. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the Food and Drug Administration (FDA).

Projects in this PE include the following:

Project 832 funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Mature COTS medical products are also evaluated for military use. Consideration will also be given to reduce the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. Products from this project will normally transition to OPA Funds.

B. Program Change Summary (\$ in Millions)

	<u>FY 2023</u>	<u>FY 2024</u>	<u>FY 2025 Base</u>	<u>FY 2025 OCO</u>	<u>FY 2025 Total</u>
Previous President's Budget	5.513	6.496	7.516	-	7.516
Current President's Budget	25.035	6.496	7.143	-	7.143
Total Adjustments	19.522	0.000	-0.373	-	-0.373
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	19.650	-			
• SBIR/STTR Transfer	-0.128	-			
• Adjustments to Budget Years	-	-	-0.373	-	-0.373

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

Project: 832: *Field Medical Systems Engineering Development*

FY 2023	FY 2024

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

Congressional Add: *Program Increase - Pre-Exposure Prophylaxis for Acute Radiation Syndrome (Prep ARS) - Medical Countermeasure (MCM)*

Congressional Add Subtotals for Project: 832

Congressional Add Totals for all Projects

	FY 2023	FY 2024
	20.000	-
	20.000	-
	20.000	-

Change Summary Explanation

Decrease in funding due to a reduction in civilian requirements.

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Exhibit R-2A, RDT&E Project Justification: PB 2025 Army										Date: March 2024		
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development			
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
832: Field Medical Systems Engineering Development	-	25.035	6.496	7.143	-	7.143	6.566	6.633	6.707	6.772	0.000	65.352
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

This Project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care. Commercially available medical products are also evaluated for military use. This project funds pivotal (conclusive) human clinical trials or mechanical engineering evaluations for effectiveness of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Project Managers also consider reductions to the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. This work is frequently completed through a laboratory/contractor team with the contractor obtaining the U.S. Food and Drug Administration (FDA) licensure for sale of the product.

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

	FY 2023	FY 2024	FY 2025
Title: Field Medical Systems Engineering Development - Medical Readiness	5.035	6.496	7.143
Description: Funding is provided for engineering and manufacturing development of medical products for diagnostic devices and testing of medical devices for use in the field.			
FY 2024 Plans: Medical Device Prototype Development and Testing (formerly Modernization of medical equipment sets): Will continue to provide rapid prototype design; fabrication; evaluation and testing; and fixes for medical and medical support products, components and systems as well as harden commercial products for use in a field environment used to sustain and support the Warfighter. Will continue to conduct Developmental Test and Evaluation (DT&E) as required by Army and DoD regulations, consisting of Environmental T&E IAW Mil-STD-810G; Performance Verification Testing; and Competitive Analysis.			
Airworthiness Testing: Will continue testing both developmental and commercial carry-on medical equipment destined for use aboard Army aircraft required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products.			
Medical Health Applications: Transitioned some more advanced applications from 6.4 - 836 to 832. Will finalize Independent Verification and Validation, Cyber Security Assessments, and Operational Assessments of performance optimization decision aid(s) for Soldier environmental exposure data collection; Clinical Practice Guidelines (CPGs) to maintain proficiency and expertise while deployed; and optimizes Soldier cold weather clothing ensemble.			
FY 2025 Plans:			

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Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2023	FY 2024	FY 2025
<p>Medical Device Prototype Development and Testing: Will continue to provide rapid prototype design; fabrication; evaluation and testing; and fixes for medical and medical support products, components and systems as well as harden commercial products for use in a field environment used to sustain and support the Warfighter. Will continue to conduct Developmental Test and Evaluation (DT&E) as required by Army and DoD regulations, consisting of Environmental T&E IAW Mil-STD-810G; Performance Verification Testing; and Competitive Analysis.</p> <p>Medical Field Systems Advanced Development (MFS AD): Begin transitioning of DMMS from Program Element 0603807A / Project 836 (Field Medical Systems Advanced Development) to 832 (Field Medical Systems Engineering Development) within program element 0604807A. Development and testing CASEVAC kit for the NGCV. Will perform air worthiness testing for both developmental and commercial carry-on medical equipment destined for use aboard Army aircraft required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products.</p> <p>FY 2024 to FY 2025 Increase/Decrease Statement: The increase of funding in FY25 is due to requirements for Division Medical Mobile Shelter (DMMS) and NGCV CASEVAC.</p>				
Accomplishments/Planned Programs Subtotals		5.035	6.496	7.143
		FY 2023	FY 2024	
Congressional Add: Program Increase - Pre-Exposure Prophylaxis for Acute Radiation Syndrome (Prep ARS) - Medical Countermeasure (MCM)		20.000	-	
FY 2023 Accomplishments: Develop a pre-exposure prophylactic medical countermeasure that will protect at risk-service members from life threatening effects of ionizing radiation. Awarded contract to Humanetics Corporation for the development of an oral suspension of BIO 300 (genistein). Initiated manufacturing of three registration batches of the active pharmaceutical ingredient (API). Initiated analytical method development activities.				
Congressional Adds Subtotals		20.000	-	
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				
D. Acquisition Strategy				
To support developing in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.				

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2025 Army												Date: March 2024			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 5				PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				832 / Field Medical Systems Engineering Development							
Management Services (\$ in Millions)				FY 2023		FY 2024		FY 2025 Base		FY 2025 OCO		FY 2025 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	63.598	1.708		3.299		2.519		-		2.519	Continuing	Continuing	Continuing
Prep ARS - MCM	TBD	TBD : TBD	-	0.501		-		-		-		-	0.000	0.501	-
Subtotal			63.598	2.209		3.299		2.519		-		2.519	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2023		FY 2024		FY 2025 Base		FY 2025 OCO		FY 2025 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various : Various	13.587	1.631		0.652		0.826		-		0.826	Continuing	Continuing	Continuing
Prep ARS - MCM Development	TBD	Humanetics Corporation : TBD	-	19.499		-		-		-		-	0.000	19.499	-
Subtotal			13.587	21.130		0.652		0.826		-		0.826	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2023		FY 2024		FY 2025 Base		FY 2025 OCO		FY 2025 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Device Prototype Development and Testing	Various	Various : Various	16.519	-		0.106		0.145		-		0.145	Continuing	Continuing	Continuing
Medical Field Systems Advanced Development (MFS AD)	TBD	Various : Various	4.808	1.696		1.783		3.653		-		3.653	0.000	11.940	-
Medical Health Applications	TBD	Various : Various	-	-		0.656		-		-		-	0.000	0.656	-
Subtotal			21.327	1.696		2.545		3.798		-		3.798	Continuing	Continuing	N/A

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Exhibit R-4, RDT&E Schedule Profile: PB 2025 Army			Date: March 2024
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>	

Event Name	FY 2023				FY 2024				FY 2025				FY 2026				FY 2027				FY 2028				FY 2029			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Medical Health Applications																												
Division Medical Mobile Shelter (DMMS)																												
Next Gen Combat Vehicle CASEVAC Kit																												
Pre-Exposure Prophylaxis for Acute Radiation Syndrome (P...																												
Prep ARS - MCM Manufacturing																												
Prep ARS - MCM Nonclinical																												
Prep ARS - MCM Clinical																												
Prep ARS - MCM Regulatory																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2025 Army		Date: March 2024
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Medical Health Applications	1	2023	4	2024
Division Medical Mobile Shelter (DMMS)	1	2025	4	2029
Next Gen Combat Vehicle CASEVAC Kit	1	2025	4	2025
Pre-Exposure Prophylaxis for Acute Radiation Syndrome (Prep ARS) - Medical Countermeasure (MCM) Award	4	2023	1	2026
Prep ARS - MCM Manufacturing	4	2023	4	2024
Prep ARS - MCM Nonclinical	2	2024	4	2025
Prep ARS - MCM Clinical	3	2024	4	2025
Prep ARS - MCM Regulatory	4	2023	1	2026