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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 4: Advanced Component Development & Prototypes (ACD&P)</i>	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv 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	-	5.598	1.602	0.582	-	0.582	1.014	1.026	1.038	1.050	0.000	11.910
808: <i>DoD Drug & Vacc Ad</i>	-	0.403	0.422	0.422	-	0.422	0.432	0.438	0.443	0.449	0.000	3.009
836: <i>Field Medical Systems Advanced Development</i>	-	5.195	1.180	0.160	-	0.160	0.582	0.588	0.595	0.601	0.000	8.901

A. Mission Description and Budget Item Justification

This Program Element (PE) funds development of medical materiel within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 (Advanced Component Development and Prototype) funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet future force requirements identified within concept documents and organizational structures. This PE also provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans. These efforts are managed by U.S. Army Medical Materiel Development Activity (USAMMDA) of the U.S. Army Medical Research and Development Command.

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	5.598	1.602	0.596	-	0.596
Current President's Budget	5.598	1.602	0.582	-	0.582
Total Adjustments	0.000	0.000	-0.014	-	-0.014
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	-0.014	-	-0.014

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

Project: 836: *Field Medical Systems Advanced Development*

Congressional Add: *Program increase - wearable medical device for Traumatic Brain Injury (TBI) prevention*

Congressional Add Subtotals for Project: 836

	FY 2023	FY 2024
	5.000	-
	5.000	-

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Exhibit R-2, RDT&E Budget Item Justification: PB 2025 Army	Date: March 2024
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Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P)</i>	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

	FY 2023	FY 2024
Congressional Add Totals for all Projects	5.000	-

Change Summary Explanation

Decrease due to alignment of medical health applications to DHA.

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Exhibit R-2A, RDT&E Project Justification: PB 2025 Army										Date: March 2024		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>				Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i>			
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
808: <i>DoD Drug & Vacc Ad</i>	-	0.403	0.422	0.422	-	0.422	0.432	0.438	0.443	0.449	0.000	3.009
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

This Project funds development of candidate medical countermeasures for endemic infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/devices. These funds support human clinical effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works and continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and accelerated recovery time once diagnosed to enhance battlefield readiness. All clinical trials are conducted in accordance with United States (U.S.) Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat of the disease within the Combatant Commands theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development and production).

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

	FY 2023	FY 2024	FY 2025
Title: DoD Drug and Vaccine Advanced Development - Medical Readiness	0.403	0.422	0.422
Description: Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention to increase medical readiness. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices			
FY 2024 Plans: Will provide Civilian Manpower support for Warfighter Health, Performance and Evacuation Project Management Office			
FY 2025 Plans: Will continue to provide Civilian Manpower support for Medical Field Systems Project Management Office (MFS PMO, formerly known as Warfighter Health, Performance and Evacuation PMO)			
Accomplishments/Planned Programs Subtotals	0.403	0.422	0.422

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

N/A

Remarks

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

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i>
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D. Acquisition Strategy

Test and evaluate in-house and commercially developed products in extensive commercial partner or government-managed clinical trials to gather data required for FDA licensure ensuring government (military) requirements are met with judicious investment.

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Exhibit R-4, RDT&E Schedule Profile: PB 2025 Army **Date:** March 2024

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i>
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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 Field Systems Project Management Office (MFS PMO...)																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2025 Army **Date:** March 2024

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i>
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Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Medical Field Systems Project Management Office (MFS PMO) Civilian Manpower support	1	2023	4	2025

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Exhibit R-2A, RDT&E Project Justification: PB 2025 Army										Date: March 2024		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>				Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i>			
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
836: <i>Field Medical Systems Advanced Development</i>	-	5.195	1.180	0.160	-	0.160	0.582	0.588	0.595	0.601	0.000	8.901
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

This Project funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care. This Project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. The Project Manager (PM) also considers factors to reduce the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. FDA regulations. Products from this project will transition to PE 0604807A (Medical Materiel/Medical Biological Defense Equipment - Eng Dev) /Project 832 (Field Medical Systems Engineering Development).

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

	FY 2023	FY 2024	FY 2025
Title: Field Medical Systems Advanced Development - Medical Readiness	0.195	1.180	0.160
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. This project provides for the advanced product development and prototyping of Army lifesaving medical field systems. Project supports development and testing of medical products and equipment for deployable forces providing future interoperability of systems on the battlefield and situational awareness of Soldier well-being. Project supports enhancements to Soldier battlefield effectiveness, survivability, and sustainment. This project also supports joint medical field systems and prolonged combat casualty care requirements.			
FY 2024 Plans: Medical Health Applications: Transitioned more advanced apps from 6.4 - 836 to 832. Will finalize software design, development, test planning, acquisition documentation, and life cycle support of mission planning mobile software apps that give Commanders the tools capable of optimizing Soldier performance and readiness and reducing the risk of costly non-battle injuries related to mental acuity, fatigue management and arctic warfare.			
Arctic Medical Capabilities: Will develop a family of casualty care and prevention systems for operation in extreme cold weather per 2021 U.S. Army Arctic Strategy, "Regaining Arctic Dominance".			
FY 2025 Plans: Division Medical Mobile Shelter (DMMS): Begin evaluating commercial infrastructure equipment and development of DMMS.			
FY 2024 to FY 2025 Increase/Decrease Statement:			

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Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2023	FY 2024	FY 2025
Funding decrease in FY25 due to transition of Medical Health Applications to DHA and extended delay in Arctic Medical Capabilities requirements.			
Accomplishments/Planned Programs Subtotals	0.195	1.180	0.160

	FY 2023	FY 2024
Congressional Add: Program increase - wearable medical device for Traumatic Brain Injury (TBI) prevention	5.000	-
FY 2023 Accomplishments: Wearable medical device for TBI Prevention- Award R&D contract to Medical Technology Enterprise Consortium (MTEC) Other Transaction Authority (OTA); Initiate protocol development for severe and penetrating TBI safety study (large animal); Purchase request for 5,000 Q-Collars for use in long-term safety study and fit/tolerability evaluations; Initiate protocol development for long-term safety study (human) and fit/tolerability evaluations; Early coordination with U.S. Army Center for Initial Military Training (CIMT) for study participants		
Congressional Adds Subtotals	5.000	-

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

N/A

Remarks

D. Acquisition Strategy

Develop 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 / 4				PE 0603807A / Medical Systems - Adv Dev				836 / Field Medical Systems Advanced 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	Not Applicable : Not applicable	50.446	-		0.466		0.012		-		0.012	Continuing	Continuing	Continuing
Subtotal			50.446	-		0.466		0.012		-		0.012	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
Program Increase - Wearable Medical Device for TBI prevention	TBD	TBD : TBD	8.000	5.000		-		-		-		-	0.000	13.000	-
Subtotal			8.000	5.000		-		-		-		-	0.000	13.000	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 Health Applications	TBD	TBD : TBD	-	0.195		0.714		-		-		-	0.000	0.909	-
Division Medical Mobile Shelter (DMMS)	TBD	TBD : TBD	-	-		-		0.148		-		0.148	0.000	0.148	-
Subtotal			-	0.195		0.714		0.148		-		0.148	0.000	1.057	N/A
Remarks															
No product/contract costs greater than \$1M individually.															
Project Cost Totals			58.446	5.195		1.180		0.160		-		0.160	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 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 836 / <i>Field Medical Systems Advanced 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)																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2025 Army		Date: March 2024
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 836 / <i>Field Medical Systems Advanced 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	2026