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

Appropriation/Budget Activity					R-1 Program Element (Number/Name)							
2040: Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P)					PE 0603807A / Medical Systems - Adv Dev							
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	-	36.006	37.053	0.598	-	0.598	1.619	0.589	1.037	1.048	0.000	77.950
808: DoD Drug & Vacc Ad	-	6.891	6.477	0.403	-	0.403	0.414	0.422	0.430	0.435	0.000	15.472
811: Mil HIV Vac&Drug Dev	-	7.740	-	-	-	-	-	-	-	-	0.000	7.740
836: Field Medical Systems Advanced Development	-	20.335	30.576	0.195	-	0.195	1.205	0.167	0.607	0.613	0.000	53.698
FF4: Counterdrug, DDR, Sys Development & Demonstration	-	0.749	-	-	-	-	-	-	-	-	0.000	0.749
VST: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.291	-	-	-	-	-	-	-	-	0.000	0.291

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)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	33.085	22.071	0.000	-	0.000
Current President's Budget	36.006	37.053	0.598	-	0.598
Total Adjustments	2.921	14.982	0.598	-	0.598
• Congressional General Reductions	-	-	-	-	-
• Congressional Directed Reductions	-	-	-	-	-
• Congressional Rescissions	-	-	-	-	-
• Congressional Adds	-	15.000	-	-	-
• Congressional Directed Transfers	-	-	-	-	-
• Reprogrammings	2.921	-	-	-	-
• SBIR/STTR Transfer	-	-	-	-	-
• Adjustments to Budget Years	-	-	0.598	-	0.598

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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 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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• FFRDC Transfer	-	-0.018	-	-	-
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Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 836: *Field Medical Systems Advanced Development*

Congressional Add: *Program increase - composite shelter*

Congressional Add: *Program increase - wearable medical device for TBI prevention*

Congressional Add: *Program increase - Freeze Dried Platelets*

Congressional Add Subtotals for Project: 836

Congressional Add Totals for all Projects

	FY 2021	FY 2022
	5.500	-
	3.000	5.000
	-	10.000
Congressional Add Subtotals for Project: 836	8.500	15.000
Congressional Add Totals for all Projects	8.500	15.000

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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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army										Date: April 2022		
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 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
808: <i>DoD Drug & Vacc Ad</i>	-	6.891	6.477	0.403	-	0.403	0.414	0.422	0.430	0.435	0.000	15.472
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). Products from this Project will transition to PE 0604807A/Project 849 at MS B.

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

	FY 2021	FY 2022	FY 2023
Title: DoD Drug and Vaccine Advanced Development	6.891	-	-
Description: Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention, early diagnosis and accelerated recovery time. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices.			
Title: DoD Drug and Vaccine Advanced Development - Medical Readiness	-	1.141	0.403
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 2022 Plans: Staphylococcus aureus Vaccine: Prepare for transition of a vaccine candidate from industry and begin planning for a Phase 2 safety and efficacy trial of the candidate in an endemic population and an adult military/traveler population. We will conduct market research, develop CRADA's with industry partners and initiate acquisition documentation.			
FY 2023 Plans: Staphylococcus aureus Vaccine: 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 National Defense			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army		Date: April 2022		
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>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737) . Funding transferred to Program Element 0604110DHA, Project Code 374E.</p> <p>Support: Provides Civilian Manpower support for Warfighter Health, Performance and Evacuation Project Management Office</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Portion of 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 National Defense Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737) . Funding transferred to Program Element 0604110DHA, Project Code 374E.</p>				
<p>Title: DoD Drug and Vaccine Advanced Development - Battlefield Care and Return to Fight</p> <p>Description: Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on early diagnosis and accelerated recovery time. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices</p> <p>FY 2022 Plans: Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): Conduct initial clinical efficacy trials and manufacturing development of the Tropical Disease and Flu and Viral Infection Diseases (FLU-VID) diagnostic panels for a man-portable device.</p> <p>Treatment for Drug Resistant Battlefield Wound Infections: Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant 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 National Defense Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737) . Funding transferred to Program Element 0604110DHA, Project Code 374E.</p>		-	5.156	-
<p>Title: FY22 SBIR/STTR Transfer</p> <p>FY 2022 Plans: Funding transferred in accordance with Title 15 USC ?638.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred in accordance with Title 15 USC ?638.</p>		-	0.180	-
Accomplishments/Planned Programs Subtotals		6.891	6.477	0.403

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army Date: April 2022

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

N/A

Remarks

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-3, RDT&E Project Cost Analysis: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 808 / DoD Drug & Vacc Ad
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Management Services (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	31.569	1.762		0.312		0.403		-		0.403	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology, : Frederick MD	8.467	2.987		0.605		-		-		-	0.000	12.059	-
FY22 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.180		-		-		-	0.000	0.180	-
Subtotal			40.036	4.749		1.097		0.403		-		0.403	Continuing	Continuing	N/A

Product Development (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Rapid Human Diagnostics	C/Various	Inbios, Inc : Seattle WA	8.431	-		-		-		-		-	0.000	8.431	-
Rapid Human Diagnostics	Various	Cepheid : CA	-	2.142		2.092		-		-		-	0.000	4.234	-
Staphylococcus aureus Vaccine	Various	TBD : TBD	-	-		0.968		-		-		-	0.000	0.968	-
Treatment for Drug Resistant Battlefield Bacterial Wound Infections	Various	TBD : TBD	-	-		2.320		-		-		-	0.000	2.320	-
Subtotal			8.431	2.142		5.380		-		-		-	0.000	15.953	N/A

Test and Evaluation (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Malaria Prophylaxis Clinical Trial	TBD	TBD : TBD	11.123	-		-		-		-		-	0.000	11.123	-
Subtotal			11.123	-		-		-		-		-	0.000	11.123	N/A

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army **Date:** April 2022

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 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027			
	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
Treatment for Drug Resistant Battlefield Fungal Wound Infections																												
Rapid Human Diagnostic																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army **Date:** April 2022

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
Treatment for Drug Resistant Battlefield Fungal Wound Infections	3	2021	4	2022
Rapid Human Diagnostic	4	2017	4	2022

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army										Date: April 2022		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>				Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</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
811: <i>Mil HIV Vac&Drug Dev</i>	-	7.740	-	-	-	-	-	-	-	-	0.000	7.740
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

Note

For Fiscal Year (FY) 2022 the program funding has transitioned to Program Element (PE) 0604807A Project 849.

A. Mission Description and Budget Item Justification

This Project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides for the planning and conduct of human clinical trials in a group of healthy volunteers to assess for safety and tolerability of medical countermeasures, how the drug/vaccine is distributed through, metabolized in, and excreted from the body, and to investigate the appropriate dose. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment. The cumulative cost of treating HIV-positive DoD personnel is estimated to be \$16.6 billion for 3000 personnel over a 50-year lifetime. All clinical trials are conducted in accordance with U.S. FDA regulations.

Research efforts are coordinated with the National Institutes of Health and the National Institute of Allergy and Infectious Diseases (NIAID), Division of Acquired Immune Deficiency Syndrome (DAIDS).

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

	FY 2021	FY 2022	FY 2023
Title: Military HIV Vaccine & Drug Development	7.740	-	-
Description: This Project funds advanced development research to develop candidate HIV vaccines, assess their safety and effectiveness in evaluations with human subjects, and protect military personnel from risks associated with HIV infection.			
Accomplishments/Planned Programs Subtotals	7.740	-	-

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

N/A

Remarks

D. Acquisition Strategy

Test and evaluate commercially developed drug/vaccine candidates in government-managed trials.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 811 / Mil HIV Vac&Drug Dev
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Management Services (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Management Services Cost	TBD	Not Applicable : Not Applicable	4.315	0.386	-	-	-	-	-	-	-	-	Continuing	Continuing	Continuing
Subtotal			4.315	0.386	-	-	-	-	-	-	-	-	Continuing	Continuing	N/A

Remarks
Not Applicable

Product Development (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Cost	TBD	Not applicable : Not applicable	5.078	-	-	-	-	-	-	-	-	-	Continuing	Continuing	Continuing
Subtotal			5.078	-	-	-	-	-	-	-	-	-	Continuing	Continuing	N/A

Support (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Support Cost	TBD	TBD : TBD	4.541	-	-	-	-	-	-	-	-	-	0.000	4.541	-
Subtotal			4.541	-	-	-	-	-	-	-	-	-	0.000	4.541	N/A

Remarks
Not Applicable

Test and Evaluation (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development T&E Cost	TBD	Janssen : Not Applicable	33.257	5.075	-	-	-	-	-	-	-	-	0.000	38.332	-

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 811 / Mil HIV Vac&Drug Dev
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Test and Evaluation (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development T&E Cost	C/CPFF	PPD : Wilmington, NC	-	2.279		-		-		-		-	0.000	2.279	-
Subtotal			33.257	7.354		-		-		-		-	0.000	40.611	N/A

Remarks
Not Applicable

	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	47.191	7.740	-	-	-	-	Continuing	Continuing	N/A

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</i>
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Event Name	FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027			
	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
Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial	FY18-FY21																											

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</i>
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Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial	1	2019	4	2021

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army										Date: April 2022		
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 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
836: <i>Field Medical Systems Advanced Development</i>	-	20.335	30.576	0.195	-	0.195	1.205	0.167	0.607	0.613	0.000	53.698
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/Project 832.

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

	FY 2021	FY 2022	FY 2023
<p>Title: Field Medical Systems Advanced Development - Program Management (PM) Warfighter Expeditionary Medicine and Treatment</p> <p>Description: Funding is provided for the development of medical devices in support of enhanced combat casualty care.</p>	10.782	-	-
<p>Title: Field Medical Systems Advanced Development - PM Warfighter Health, Performance and Evacuation</p> <p>Description: Funding is provided for the development of products that support the medical mission in combat casualty care and health care operations.</p>	1.053	-	-
<p>Title: Field Medical Systems Advanced Development - Medical Readiness</p> <p>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.</p> <p>FY 2022 Plans: Non-invasive Neuro Assessment Devices (NINAD): Will complete an analysis of alternatives report. Will award R&D contract for development of NINAD capability. Will initiate bench performance testing to demonstrate adequate performance in the laboratory. Will begin protocol development and infrastructure preparation for field evaluation / clinical trial(s) to demonstrate effectiveness in a defined Traumatic Brain Injury population to enable U.S. FDA approval.</p> <p>FY 2023 Plans: Soldier Optimization Decision Aids (SODA): Initiate 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 potential and reducing the risk of costly non-battle injuries</p>	-	4.103	0.195

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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>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Non-invasive Neuro Assessment Devices (NINAD): 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 National Defense Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0604110DHA, Project Code 374E.</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 National Defense Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0604110DHA, Project Code 374E.</p>				
<p>Title: Field Medical Systems Advanced Development - Battlefield Care and Return to Fight</p> <p>Description: Funding is provided for the development of the medical devices and blood products in support of enhanced combat casualty care.</p> <p>FY 2022 Plans: Temporary Corneal Repair: Will continue initial clinical trials and conduct activities to support FDA clearance of TCR product. Will perform developmental and military-relevant testing of product candidates. Extracorporeal Life Support - Lung/Renal: Closing out current contract activities in FY21. Candidate returned to technology base for refinement to meet MDO CONOPS. Burn Treatment Skin Repair- Burn Conversion Prevention: Will award prototyping agreements for products needed to treat severe burns in prolonged care scenarios Freeze Dried Platelets: Conduct market research, develop CRADA's with industry partners and initiate acquisition documentation for a candidate from industry and begin planning for a Phase 2 safety and efficacy trial of the candidate.</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 National Defense Authorization Act 2019 (Sections 711) and NDAA 2020 (Section 737). Funding transferred to Program Element 0604110DHA, Project Code 374E.</p>		-	5.819	-
<p>Title: Field Medical Systems Advanced Development - Field Hospital and Evacuation</p> <p>Description: Funding is provided for the development of medical devices in support of the medical mission field hospitalization and evacuation.</p> <p>FY 2022 Plans:</p>		-	5.149	-

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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>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Transport Telemedicine Systems (TTS): Will start TTS MEDHUB (Medical Hands-Free Unified Broadcast) Increment 2, which will focus on FDA approval and development (ruggedization for a high vibration environment, etc) of peripheral medical devices that will communicate with MEDHUB. The peripheral medical devices include Drug Safety and Tracking System, Intravenous Pressure Infuser and Blood Pressure Monitor. FY 2022 to FY 2023 Increase/Decrease Statement: Decrease in funding due to termination of TTS effort as the result of a shift in Army priorities and contract closeout.				
Title: SBIR/STTR Tax FY 2022 Plans: Funding transferred in accordance with Title 15 USC ?638. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred in accordance with Title 15 USC ?638.		-	0.505	-
Accomplishments/Planned Programs Subtotals		11.835	15.576	0.195
		FY 2021	FY 2022	
Congressional Add: Program increase - composite shelter FY 2021 Accomplishments: Started development and testing for advanced fully composite shelters to improve Hospital Center operations.		5.500	-	
Congressional Add: Program increase - wearable medical device for TBI prevention FY 2021 Accomplishments: Funding reprogrammed from 6.5 to 6.4. Developed full and open solicitation and released for proposals to develop capability for US Military-unique needs. FY 2022 Plans: Continue development and systems engineering of ?Wearable TBI Device? to fulfill US Military-unique needs for TBI prevention; including developmental testing, pre-clinical testing and prototype refinement, environmental testing to ensure conformance to specs, FDA meeting(s), and Military Utility Assessment (MUA) activities.		3.000	5.000	
Congressional Add: Program increase - Freeze Dried Platelets FY 2022 Plans: Will support a Phase 2a clinical trial in civilian trauma that translates to further prehospital studies with further use in combat to prevent loss of life. This study would provide the pilot data needed to		-	10.000	

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army	Date: April 2022
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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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	FY 2021	FY 2022
support development and conduct of a pivotal Phase2/3 human clinical trial in trauma and the development of unique packaging for extreme environments.		
Congressional Adds Subtotals	8.500	15.000

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 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 836 / Field Medical Systems Advanced Development
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Management Services (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	48.310	0.572		1.564		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/IDIQ	Not applicable : Not applicable	2.295	-		0.150		-		-		-	0.000	2.445	-
FY22 SBIR/STTR Transfer	TBD	various : Various	-	-		0.505		-		-		-	0.000	0.505	-
Subtotal			50.605	0.572		2.219		-		-		-	Continuing	Continuing	N/A

Product Development (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Temporary Corneal Repair	C/Various	Critical Innovations, LLC, GelMEDIX, Endomedix, Inc., Ashvattha Therapeutics, LLC , University of Southern California, Institute of Surgical Research : Inglewood, CA, Cambridge, MA, Montclair, NJ, Redwo	9.259	4.462		2.178		-		-		-	0.000	15.899	-
Extracorporeal Life Support (ECLS)	Various	Medical Technology Enterprise Consortium : Summerville SC	0.558	3.150		-		-		-		-	0.000	3.708	-
Non-invasive neuro assessment device (NINAD)	C/Various	TBD : TBD	0.800	-		1.471		-		-		-	0.000	2.271	-

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army												Date: April 2022			
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							
Product Development (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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
Transport Telemedicine Systems (TTS) - MEDHUB Platform	TBD	Cooper Consulting Services : TBD	2.286	0.057		2.899		-		-		-	Continuing	Continuing	Continuing
Extremity Injury Repair - Vascular	TBD	SS/CPFF : HumaCyte: Morrisville, NC	6.610	2.531		-		-		-		-	Continuing	Continuing	Continuing
Burn Treatment Skin Repair	TBD	TBD : TBD	-	-		2.760		-		-		-	0.000	2.760	-
Platelet-Derived Hemostatic Agent	TBD	TBD : TBD	-	-		0.316		-		-		-	0.000	0.316	-
Program Increase - Wearable Medical Device for TBI prevention	TBD	TBD : TBD	-	3.000		5.000		-		-		-	0.000	8.000	-
Program increase - composite shelter	TBD	OSD-MRO : TBD	-	5.296		-		-		-		-	0.000	5.296	-
Program increase - Freeze Dried Platelets	TBD	TBD : TBD	-	-		10.000		-		-		-	0.000	10.000	-
Subtotal			19.513	18.496		24.624		-		-		-	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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 Support Cost	Various	Not Applicable : Not applicable	51.199	1.173		1.842		-		-		-	Continuing	Continuing	Continuing
Program increase - composite shelter	TBD	TBD : TBD	-	0.094		-		-		-		-	0.000	0.094	-
Soldier Optimization Decision Aid	TBD	TBD : TBD	-	-		-		0.195		-		0.195	0.000	0.195	-
Subtotal			51.199	1.267		1.842		0.195		-		0.195	Continuing	Continuing	N/A

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army **Date:** April 2022

Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 836 / Field Medical Systems Advanced Development
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Support (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			

Remarks
No product/contract costs greater than \$1M individually.

Test and Evaluation (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Noninvasive Neuro-Assessment Devices (NINAD)	TBD	TBD : TBD	-	-		1.891		-		-		-	0.000	1.891	-
Subtotal			-	-		1.891		-		-		-	0.000	1.891	N/A

Remarks
No product/contract costs greater than \$1M individually.

	Prior Years	FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract										
Project Cost Totals											121.317	20.335		30.576		0.195		-		0.195	Continuing	Continuing	N/A

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army			Date: April 2022		
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 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027			
	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
Temporary Corneal Repair																												
	R&D development																											
Temporary Corneal Repair -Prototype Testing	Prototype Testing																											
Temporary Corneal Repair- Clinical Study	Clinical Study																											
Noninvasive Neuro Assessment Device development (NINAD)	R&D development																											
Transport Telemedicine Systems (TTS)- MEDHUB Platform																												
Burn Treatment Skin Repair					Prototype Development																							

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
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
Temporary Corneal Repair	2	2016	4	2022
Temporary Corneal Repair -Prototype Testing	2	2018	4	2022
Temporary Corneal Repair- Clinical Study	2	2020	4	2022
Noninvasive Neuro Assessment Device development (NINAD)	1	2019	4	2022
Transport Telemedicine Systems (TTS)- MEDHUB Platform	3	2013	4	2022
Burn Treatment Skin Repair	1	2022	4	2022

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army										Date: April 2022		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) FF4 / Counterdrug, DDR, Sys Development & Demonstration			
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
FF4: Counterdrug, DDR, Sys Development & Demonstration	-	0.749	-	-	-	-	-	-	-	-	0.000	0.749
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

Supports the Secretary of Defense approved counterdrug advanced development efforts used in a major re-design of the Forensic Toxicology Drug Testing Laboratory (FTDTL) information management system used to test urine samples for the presence of illegal drugs. The Drug Testing Program - Client Collection System (DTP-CSS) is comprised of several variations of a desktop application used to select service members for random drug testing, prepare labels for urine specimen bottles, and print corresponding chain-of-custody documents. This Project will standardize DTP-CSS across all services and migrate it to a Web-based system.

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

	FY 2021	FY 2022	FY 2023
Title: Forensic Toxicology Drug Testing Laboratory- Information Management System system.(FTDTL-IMS)	0.749	-	-
Accomplishments/Planned Programs Subtotals	0.749	-	-

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

N/A

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army		Date: April 2022
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) FF4 / Counterdrug, DDR, Sys Development & Demonstration

FY 2014				FY 2015				FY 2016				FY 2017				FY 2018				FY 2019				FY 2020			
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

Determine Hosting requirements			
Coding and Development Testing			
User Testing			

FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027			
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

Determine Hosting requirements			
Coding and Development Testing			
User Testing			

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) FF4 / <i>Counterdrug, DDR, Sys Development & Demonstration</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Determine Hosting requirements	2	2017	2	2017
Coding and Development Testing	3	2017	1	2019
User Testing	1	2019	2	2019

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army										Date: April 2022		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>				Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</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
<i>VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>	-	0.291	-	-	-	-	-	-	-	-	0.000	0.291
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

This Project is funded to achieve the required operational capability and common capability across the MEDEVAC fleet. The MEDEVAC MEP program modernizes and retrofits MEDEVAC legacy helicopters to achieve the medical capability provided by a limited number of mission specific MEDEVAC helicopters, to include Blackhawk and Future Vertical Lift. The Medevac Mission Equipment on the Army MEDEVAC helicopters is critical to maintaining high US troop survival rates during current and future conflicts by evacuating wounded troops quickly while providing good care enroute. To better meet operational needs, in 2009 the Vice Chief of Staff of the Army (VCSA) approved the force design update increasing the number of air frames for MEDEVAC companies. In 2010, the Army Medical Department (US Army) accepted life-cycle management of the MEDEVAC MEP from PEO Aviation. Ongoing research and design efforts are required to prepare and optimize the MEDEVAC fleet with mission equipment. All products from this Project will transition to PE 0604807A/Project VS8.

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

	FY 2021	FY 2022	FY 2023
Title: Medical Evacuation Development	0.291	-	-
Description: This effort involves Aeromedical Evacuation Cabin and Technology Research to determine the optimum space and configuration for performing necessary life-saving paramedic-level tasks. Efforts will develop patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers' lives during point of injury MEDEVAC Missions.			
Accomplishments/Planned Programs Subtotals	0.291	-	-

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 MEDEVAC and regulatory requirements for production and fielding.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army												Date: April 2022			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 4				PE 0603807A / Medical Systems - Adv Dev				VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev							
Management Services (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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 Services Cost	Various	APM MEDEVAC PEO Aviation : Huntsville, AL	3.665	0.291		-		-		-		-	0.000	3.956	-
Subtotal			3.665	0.291		-		-		-		-	0.000	3.956	N/A
Product Development (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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	TBD	APM MEDEVAC PEO Aviation : Huntsville AL	4.651	-		-		-		-		-	0.000	4.651	-
Subtotal			4.651	-		-		-		-		-	0.000	4.651	N/A
Support (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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 Support Cost	TBD	APM MEDEVAC PEO Aviation : Huntsville, AL	0.911	-		-		-		-		-	0.000	0.911	-
Subtotal			0.911	-		-		-		-		-	0.000	0.911	N/A
Test and Evaluation (\$ in Millions)				FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 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 T&E Cost	MIPR	APM MEDEVAC PEO Aviation : Huntsville, AL	0.199	-		-		-		-		-	0.000	0.199	-
Subtotal			0.199	-		-		-		-		-	0.000	0.199	N/A

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2023 Army								Date: April 2022					
Appropriation/Budget Activity 2040 / 4				R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>				Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>					
	Prior Years	FY 2021		FY 2022		FY 2023 Base		FY 2023 OCO		FY 2023 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	9.426	0.291		-		-		-		-	0.000	9.717	N/A

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army			Date: April 2022
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>	

Event Name	FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027			
	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
Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Sp	Research and development																											

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Space and Technology	1	2017	4	2021