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Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army **Date:** May 2021

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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
Total Program Element	-	70.489	51.285	44.424	-	44.424	-	-	-	-	-	-
812: <i>Mil HIV Vac&Drug Dev</i>	-	1.152	1.184	-	-	-	-	-	-	-	-	-
832: <i>Field Medical Systems Engineering Development</i>	-	29.623	34.244	27.461	-	27.461	-	-	-	-	-	-
849: <i>Infec Dis Drug/Vacc Ed</i>	-	39.714	15.857	16.963	-	16.963	-	-	-	-	-	-

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 812 funds military relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development focused on military unique needs effecting manning, mobilization, and deployment. Products from this project will normally transition to Department of Defense (DoD) Health Programs or Other Procurement, Army (OPA) Funds.

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.

Project 849 funds development of candidate medical countermeasures for military relevant infectious diseases. These products fall in four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. Products from this project will normally transition to DoD Health Programs or OPA funds.

These Projects are managed by United States (U.S.) Army Medical Materiel Development Activity (USAMMDA) and United States (U.S.) Army Medical Materiel Agency (USAMMA) of the U.S. Army Medical Research and Materiel Command.

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B. Program Change Summary (\$ in Millions)	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total
Previous President's Budget	48.264	49.870	46.860	-	46.860
Current President's Budget	70.489	51.285	44.424	-	44.424
Total Adjustments	22.225	1.415	-2.436	-	-2.436
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	3.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	23.952	-			
• SBIR/STTR Transfer	-1.727	-1.585			
• Adjustments to Budget Years	-	-	-2.436	-	-2.436

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

Project: 832: *Field Medical Systems Engineering Development*

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

	FY 2020	FY 2021
	-	3.000
Congressional Add Subtotals for Project: 832	-	3.000
Congressional Add Totals for all Projects	-	3.000

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

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) 812 / <i>Mil HIV Vac&Drug Dev</i>
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
812: <i>Mil HIV Vac&Drug Dev</i>	-	1.152	1.184	-	-	-	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-	-	-

Note
Funding realigned in Fiscal Year (FY) 2022 to Program Element (PE) 0604807A Project 849.

A. Mission Description and Budget Item Justification

This Project funds militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development is focused on militarily unique needs effecting manning, mobilization, and deployment.

The major contractor is The Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.

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

	FY 2020	FY 2021	FY 2022
Title: Military HIV Vaccine and Drug Development	1.152	1.184	-
Description: This effort provides funds for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing of vaccines for medical countermeasures to HIV.			
FY 2021 Plans: Continue support to Global Vaccine Candidate clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.			
FY 2021 to FY 2022 Increase/Decrease Statement: The decrease of funding in FY22 was due to realignment of this effort to PE 0604807A / Project 849.			
Accomplishments/Planned Programs Subtotals	1.152	1.184	-

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

N/A

Remarks

D. Acquisition Strategy

To support testing and evaluation of commercially developed vaccine candidates in government-managed trials.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army												Date: May 2021			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 5				PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				812 / Mil HIV Vac&Drug Dev							
Management Services (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	3.229	0.448		1.184		-		-		-	Continuing	Continuing	-
Subtotal			3.229	0.448		1.184		-		-		-	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Henry M. Jackson Foundation, : Various	33.967	-		-		-		-		-	Continuing	Continuing	Continuing
Subtotal			33.967	-		-		-		-		-	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Various : Various	2.413	-		-		-		-		-	Continuing	Continuing	-
Regulatory Support	Option/Various	Clinical Research Management, Inc : Various	0.900	0.009		-		-		-		-	0.000	0.909	-
Subtotal			3.313	0.009		-		-		-		-	Continuing	Continuing	N/A
Test and Evaluation (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Various	Various : Various	28.789	0.695		-		-		-		-	Continuing	Continuing	Continuing
Subtotal			28.789	0.695		-		-		-		-	Continuing	Continuing	N/A

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army							Date: May 2021				
Appropriation/Budget Activity 2040 / 5			R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 812 / Mil HIV Vac&Drug Dev				
	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	Cost To Complete	Total Cost	Target Value of Contract		
Project Cost Totals	69.298	1.152	1.184	-	-	-	Continuing	Continuing	N/A		

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2022 Army			Date: May 2021
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) 812 / <i>Mil HIV Vac&Drug Dev</i>	

Event Name	FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026			
	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																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2022 Army		Date: May 2021
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) 812 / <i>Mil HIV Vac&Drug Dev</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Global HIV	1	2021	4	2021

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Army										Date: May 2021		
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 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
832: Field Medical Systems Engineering Development	-	29.623	34.244	27.461	-	27.461	-	-	-	-	-	-
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, including rehabilitation. Mature commercial off the shelf (COTS) medical products are also evaluated for military use. Specifically 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. Consideration is also given to reducing 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 2020	FY 2021	FY 2022
<p>Title: Field Medical Systems Engineering Development PM Warfighter Deployed Medical Systems</p> <p>Description: Funding is provided for modernization of Sets, Kits and Outfits.</p> <p>FY 2021 Plans: Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment will be selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to internal restructure within PE 0604807A, Project 832.</p>	-	1.676	-
<p>Title: Field Medical Systems Engineering Development PM Warfighter Protection and Acute Care</p> <p>Description: Funding is provided for engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including blood products.</p> <p>FY 2021 Plans: Cryopreserved Platelets: Will continue the new acquisition strategy that was developed and implemented in FY 2018 where a single commercial partner is utilized for the manufacturing development, clinical trials and regulatory processes thru licensure. Will continue non-clinical in-Vitro characterization and Phase 2 Clinical Trial efficacy study.</p>	11.357	14.430	-

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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 2020	FY 2021	FY 2022
Freeze-Dried Plasma Program: Will complete the Phase 2 safety and effectiveness study and prepare for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study. FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to internal restructure within PE 0604807A, Project 832.				
<p>Title: Field Medical Systems Engineering Development PM Warfighter Health, Performance and Evacuation (formerly PM Medical Support Systems)</p> <p>Description: This project funds the engineering and manufacturing development of medical products for prevention of injury, enhanced combat casualty care, and evacuation.</p> <p>FY 2021 Plans: Modernization of medical equipment sets: Will complete modernization and evaluation of the Field Hospital water distribution and waste water management system and blood transport products. Will continue evaluation of other commercial items for medical equipment sets.</p> <p>Airworthiness Testing: Will conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products covering air evacuation.</p> <p>Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package and CASEVAC: Will complete design and evaluation of the CASEVAC system for the JLTV</p> <p>Soldier Optimization Decision Aids (SODA): Will coordinate with PEO Soldier to transition the Mental Acuity, Environmental Exposure Electronic (E3) form (formerly Environment Health Assessment and Risk Management (EHARM) tool) and the Cold Weather Ensemble Decision Aid.</p> <p>Next Generation Uniform Repellent/Impregnation: Will complete project and transition to PEO Soldier.</p> <p>Litter Transport Shock/Stressor Mitigation System (Formerly: Next Generation Immobilization System): Project concluded in FY 2018 with transition to the Air Force.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to internal restructure within PE 0604807A, Project 832.</p>		6.262	4.621	-
Title: Field Medical Systems Engineering Development - PM Warfighter Brain Health		12.004	10.517	-

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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 2020	FY 2021	FY 2022
<p>Description: This effort funds systems engineering development of medical products for enhanced combat casualty care for diagnosis of Traumatic Brain Injury (TBI).</p> <p>FY 2021 Plans: Laboratory Assay for TBI - Point of Care (formerly TBI Diagnostic Assay System): Will continue validation studies for testing of a blood assay to aid in the diagnosis of TBI. Will finalize FDA submission of the assay for Food and Drug Administration approval. Will finalize data analysis and report on the assay's ability to predict recovery from TBI.</p> <p>Non-invasive neuro assessment device (NINAD): Moved to WBH due to PMO Reorganization. Will initiate developmental testing and initial operational assessments based on FDA approval and maturity of other commercially available products.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to internal restructure within PE 0604807A, Project 832.</p>				
<p>Title: Field Medical Systems Engineering 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: Laboratory Assay for Traumatic Brain Injury (TBI) - Point of Care: Will complete validation studies for testing of a blood assay to aid in the diagnosis of TBI. Medical Device Testing (formerly Modernization of medical equipment sets): Will continue to conduct test and evaluation of commercial items for medical equipment sets as required by AR 73-1 and DoD 5000. Airworthiness Testing: Will continue to conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to internal restructure within PE 0604807A, Project 832.</p>		-	-	11.621
<p>Title: Field Medical Systems Engineering Development - Battlefield Care and Return to Fight</p> <p>FY 2022 Plans: Handheld Ultrasound: Will conduct testing and evaluation of prototype devices. This will inform the selection of a device that meets Army requirements. Extremity Injury Repair - Vascular: Will complete FDA clinical studies and submit application to FDA for approval. Will also conduct stability testing for operational environment.</p>		-	-	15.840

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
<p>Cryopreserved Platelets: Will continue non-clinical in-Vitro characterization and Phase 2 Clinical Trial efficacy study.</p> <p>Freeze-Dried Plasma Program: Due to an unexpected delay in phase 2 safety and effectiveness study initiation, will complete Phase 2 safety and effectiveness study originally scheduled for completion in FY21. Will prepare for initiation of Phase 3 (expanded safety, effectiveness and dosing) pivotal study.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to internal restructure within PE 0604807A, Project 832.</p>			
Accomplishments/Planned Programs Subtotals	29.623	31.244	27.461

	FY 2020	FY 2021
Congressional Add: Program increase - wearable medical device for TBI prevention	-	3.000
FY 2021 Plans: Will commit resources to validate requirements & award a competitive contact to mature a wearable TBI medical device system that will protect service members from TBI injury in austere joint, all-domain operations		
Congressional Adds Subtotals	-	3.000

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 2022 Army												Date: May 2021			
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 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	45.245	8.407		6.336		2.850		-		2.850	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology : Frederick MD	-	0.752		0.300		0.300		-		0.300	0.000	1.352	-
Subtotal			45.245	9.159		6.636		3.150		-		3.150	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	10.928	-		-		0.691		-		0.691	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	1.875	5.236		4.127		3.534		-		3.534	0.000	14.772	-
Laboratory Assay for Traumatic Brain Injury	C/Various	Abbott Laboratories : Chicago, IL	13.211	8.432		7.271		-		-		-	Continuing	Continuing	Continuing
Laboratory Assay for Traumatic Brain Injury	TBD	Abbot Laboratories : Chicago, Ill	-	-		-		6.680		-		6.680	0.000	6.680	-
Handheld Ultrasound	Various	TBD : TBD	-	-		-		1.461		-		1.461	Continuing	Continuing	Continuing
Extremity Injury Repair - Vascular	TBD	Humacyte : Morrisville, NC	-	-		-		2.656		-		2.656	0.000	2.656	-
Freeze Dried Plasma	C/FFP	Vascular Solutions : Maple Grove, MN	-	1.174		-		-		-		-	0.000	1.174	-
Program increase - wearable medical device for TBI prevention	TBD	TBD : TBD	-	-		3.000		-		-		-	0.000	3.000	-
Subtotal			26.014	14.842		14.398		15.022		-		15.022	Continuing	Continuing	N/A

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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							
Support (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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
Regulatory Support	Various	Clinical Research Management, Inc., : Various	8.760	0.309		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various : Various	11.729	1.948		0.730		-		-		-	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various : Various	2.670	-		1.310		-		-		-	0.000	3.980	-
Airworthiness Certification	TBD	Various : Various	-	1.374		-		1.823		-		1.823	0.000	3.197	-
Soldier Optimization Decision Aid	TBD	Various : Various	-	1.000		-		-		-		-	0.000	1.000	-
Subtotal			23.159	4.631		2.040		1.823		-		1.823	Continuing	Continuing	N/A
Test and Evaluation (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Various	Various : Various	18.291	-		0.500		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	C/CPFF	Cellphire : Rockville, MD	17.996	-		4.105		1.246		-		1.246	0.000	23.347	-
Medical Equipment Sets Development	Various	Various : Various	5.014	0.691		1.456		-		-		-	0.000	7.161	-
Freeze Dried Plasma	C/CPFF	Westat : Rockville, MD	14.691	0.300		5.109		6.220		-		6.220	0.000	26.320	-
Subtotal			55.992	0.991		11.170		7.466		-		7.466	Continuing	Continuing	N/A
Project Cost Totals			150.410	29.623		34.244		27.461		-		27.461	Continuing	Continuing	N/A
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2022 Army		Date: May 2021
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

Event Name	FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026			
	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
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies	Phase 2																											
Cryopreserved Platelets (CPP) Phase III clinical studies	Phase 3																											
Freeze-dried Plasma (FDP) Phase I safety clinical studies	Phase I																											
Freeze-dried Plasma (FDP) Phase 2 efficacy clinical studies	Phase 2																											
Laboratory Assay for TBI Point of Care Device Clinical Trial	Clinical Trial																											
Laboratory Assay for TBI Point of Care Device MS C	MS-C																											
Extremity Injury Repair - Vascular- Pivotal Study	Vascular- Pivotal Study																											
Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing	Vascular- Environmental Testing/Operational Testing																											
Handheld Ultrasound - RMF Ruggedization, LRIP, and IOT&E	RMF Ruggedization, LRIP, and IOT&E																											

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Exhibit R-4A, RDT&E Schedule Details: PB 2022 Army		Date: May 2021
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
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies	3	2017	4	2024
Cryopreserved Platelets (CPP) Phase III clinical studies	4	2021	3	2023
Freeze-dried Plasma (FDP) Phase I safety clinical studies	3	2014	2	2021
Freeze-dried Plasma (FDP) Phase 2 efficacy clinical studies	2	2016	1	2023
Laboratory Assay for TBI Point of Care Device Clinical Trial	1	2021	4	2022
Laboratory Assay for TBI Point of Care Device MS C	2	2021	2	2021
Extremity Injury Repair - Vascular- Pivotal Study	1	2019	1	2023
Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing	1	2022	4	2023
Handheld Ultrasound - RMF Ruggedization, LRIP, and IOT&E	1	2022	4	2024

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Army **Date:** May 2021

Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
849: <i>Infec Dis Drug/Vacc Ed</i>	-	39.714	15.857	16.963	-	16.963	-	-	-	-	-	-
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-	-	-

A. Mission Description and Budget Item Justification

This Project funds development of candidate medical countermeasures (MCM: e.g., vaccines, drugs, diagnostic kits/devices) for militarily relevant infectious diseases. It funds research that supports conclusive human clinical trials to demonstrate MCM effectiveness safety and related manufacturing tests. This work, which is jointly performed by military laboratories, civilian contracted pharmaceutical firms and foreign research partners, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. Medical products approved for human use must meet the United States (U.S.) Food and Drug Administration (FDA) approval before MCM can be used on Warfighters. Development priority is based upon four major factors: (1) the extent 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, production, and sustainment). Malaria, dysentery and dengue diseases (a severe debilitating disease transmitted by mosquitoes), which are found in all Combatant Command areas and are at the top of the infectious diseases risks list.

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

	FY 2020	FY 2021	FY 2022
<p>Title: Infectious Disease Drug and Vaccine Engineering Development</p> <p>Description: Funding for research and development efforts for drugs and vaccines for infectious diseases that are top threats to deployed US forces. Funds research that supports conclusive human clinical trials to demonstrate effectiveness, safety and related manufacturing tests.</p> <p>FY 2021 Plans: Dengue Vaccine Effort: Will continue to fund support for Advance Development (AD) candidate vaccine for the expanded FDA safety/effectiveness/dosing study in humans.</p> <p>Malaria Prophylactic Drug ? Tafenoquine (TQ) (Formerly Next Generation Malaria Prophylaxis): Achieved MS C in FY19. Will address any remaining FDA post-marketing approval requirements.</p> <p>Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Project terminated in FY 2019.</p> <p>Rapid Diagnostic and Detection Devices: The dengue and chikungunya assays will continue to be developed and evaluated. Clinical testing for dengue will continue.</p>	15.297	15.857	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Army		Date: May 2021		
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) 849 / <i>Infec Dis Drug/Vacc Ed</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2020	FY 2021	FY 2022
<p>Tick-Bourne Encephalitis Vaccine (TBEVV): Develop Pfizer's European Medicines Agency approved TBEVV for FDA licensure following commercial partner agreement.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Decrease due to internal restructure within PE 0604807A, Project 849.</p>				
<p>Title: Infectious Disease Drug and Vaccine Engineering Development - Medical Readiness</p> <p>Description: Funding is provided for the development of candidate medical countermeasures for military relevant infectious diseases focusing on prevention to increase medical readiness. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of vaccines.</p> <p>FY 2022 Plans: Dengue Vaccine Effort: Fund post licensure activities required by the FDA for use of the vaccine in military populations. Malaria Chemoprophylaxis -Tafenoquine (formerly Next Generation Malaria Prophylaxis): Will continue to address any remaining FDA post-marketing requirements. Tick-Bourne Encephalitis Vaccine (TBEVV): Industry Developer will pursue FDA approval on it's own. Human Immunodeficiency Virus Vaccine (HIVV): Program and funding moved from Project 0603807A 811 and Project 643807A 812. Will continue to support clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to internal restructure within PE 0604807A, Project 849.</p>		-	-	12.720
<p>Title: Infectious Disease Drug and Vaccine Engineering Development - Battlefield Care and Return to Fight</p> <p>Description: Funding for research and development efforts for drugs for treatment and devices for early diagnosis for infectious diseases that are top threats to deployed US forces. Funds research that supports conclusive human clinical trials to demonstrate effectiveness, safety and related manufacturing tests</p> <p>FY 2022 Plans: Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple): Begin planning Phase III clinical trials and final manufacturing development of the Tropical Disease and Flu and Viral Infection Diseases (FLU-VID) diagnostic panels for a man-portable device.</p> <p>FY 2021 to FY 2022 Increase/Decrease Statement: Increase due to internal restructure within PE 0604807A, Project 849.</p>		-	-	4.243
Title: Infectious Disease Drug and Vaccine Engineering Development - CARES ACT		24.417	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2022 Army		Date: May 2021
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) 849 / <i>Infec Dis Drug/Vacc Ed</i>

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2020	FY 2021	FY 2022
Accomplishments/Planned Programs Subtotals	39.714	15.857	16.963

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

N/A

Remarks

D. Acquisition Strategy

To support testing and evaluation of in-house and commercially developed products in government-managed trials to meet FDA requirements.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army												Date: May 2021			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 5				PE 0604807A / Medical Materiel/Medical B iological Defense Equipment - Eng Dev				849 / Infec Dis Drug/Vacc Ed							
Management Services (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	25.359	3.590		0.500		0.500		-		0.500	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	12.471	1.871		1.500		1.984		-		1.984	0.000	17.826	-
Subtotal			37.830	5.461		2.000		2.484		-		2.484	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	39.557	2.439		-		-		-		-	Continuing	Continuing	Continuing
Dengue Tetravalent Vaccine	TBD	TBD : TBD	2.047	-		-		-		-		-	0.000	2.047	-
Rapid Diagnostic and Detection Devices	Various	Inbios, Inc : Seattle WA	-	3.443		3.673		3.700		-		3.700	0.000	10.816	-
CARES ACT	TBD	TBD : TBD	-	24.417		-		-		-		-	0.000	24.417	-
Subtotal			41.604	30.299		3.673		3.700		-		3.700	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Various : Various	19.392	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Support Cost	PO	Clinical Research Management, In : Hinckley, OH	6.438	0.166		-		-		-		-	0.000	6.604	-
Subtotal			25.830	0.166		-		-		-		-	Continuing	Continuing	N/A

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army **Date:** May 2021

Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed
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Test and Evaluation (\$ in Millions)				FY 2020		FY 2021		FY 2022 Base		FY 2022 OCO		FY 2022 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	Various	Various : Various	51.320	-		-		-		-		-	Continuing	Continuing	Continuing
Dengue Tetravalent Vaccine	TBD	WRAIR/AFRIMS : Silver Spring MD	1.788	0.861		0.390		0.861		-		0.861	0.000	3.900	-
Dengue Tetravalent Vaccine	C/TBD	BioPath : Philippines	5.974	0.770		0.750		1.017		-		1.017	0.000	8.511	-
Product Development of Dengue Tetravalent Vaccine	Various	TBD : TBD	4.530	-		-		-		-		-	0.000	4.530	-
Next Generation Malaria Prophylaxis	Various	DVC : Frederick MD	3.228	2.157		2.729		3.695		-		3.695	0.000	11.809	-
Tick-Borne Encephalitis Vaccine	Various	TBD : TBD	-	-		4.238		-		-		-	0.000	4.238	-
Norovirus Vaccine	Various	TBD : TBD	-	-		2.077		-		-		-	0.000	2.077	-
Human Immunodeficiency Virus Vaccine (HIVV)	Various	Janssen Vaccines & Prevention B.V. : Netherlands	-	-		-		3.544		-		3.544	0.000	3.544	-
Human Immunodeficiency Virus Vaccine (HIVV)	TBD	PPD : Wilmington, NC	-	-		-		1.662		-		1.662	0.000	1.662	-
Subtotal			66.840	3.788		10.184		10.779		-		10.779	Continuing	Continuing	N/A

Project Cost Totals	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	Cost To Complete	Total Cost	Target Value of Contract
	172.104	39.714	15.857	16.963	-	16.963	Continuing	Continuing	N/A

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2022 Army		Date: May 2021
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed

Event Name	FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025				FY 2026			
	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
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trial	[Redacted]				[Redacted]																							
Dengue Tetravalent Vaccine (MS-C)					 MS-C																							
Dengue Tetravalent Vaccine EMD					[Redacted]																							
Rapid Human Diagnostic Devices	[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]							
Malaria Prophylaxis Post FDA Approval Marketing Studies	[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]							
Global HIV Phase 2B Clinical Trial	[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]							
Global HIV Phase 3 Efficacy Clinical Trial	[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]				[Redacted]							

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Exhibit R-4A, RDT&E Schedule Details: PB 2022 Army		Date: May 2021
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) 849 / <i>Infec Dis Drug/Vacc Ed</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials	1	2012	2	2020
Dengue Tetravalent Vaccine (MS-C)	2	2021	2	2021
Dengue Tetravalent Vaccine EMD	3	2020	4	2022
Rapid Human Diagnostic Devices	1	2020	4	2025
Malaria Prophylaxis Post FDA Approval Marketing Studies	4	2019	4	2023
Global HIV Phase 2B Clinical Trial	1	2022	1	2023
Global HIV Phase 3 Efficacy Clinical Trial	1	2023	1	2026