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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 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 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	-	48.285	44.400	5.513	-	5.513	6.598	7.615	7.011	7.078	0.000	126.500
812: <i>Mil HIV Vac&Drug Dev</i>	-	1.184	-	-	-	-	-	-	-	-	0.000	1.184
832: <i>Field Medical Systems Engineering Development</i>	-	31.244	27.437	5.513	-	5.513	6.598	7.615	7.011	7.078	0.000	92.496
849: <i>Infec Dis Drug/Vacc Ed</i>	-	15.857	16.963	-	-	-	-	-	-	-	0.000	32.820

A. Mission Description and Budget Item Justification

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

Projects in this PE include the following:

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

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) of the U.S. Army Medical Research and Development Command.

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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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B. Program Change Summary (\$ in Millions)	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023 Base</u>	<u>FY 2023 OCO</u>	<u>FY 2023 Total</u>
Previous President's Budget	51.285	44.424	0.000	-	0.000
Current President's Budget	48.285	44.400	5.513	-	5.513
Total Adjustments	-3.000	-0.024	5.513	-	5.513
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-3.000	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	5.513	-	5.513
• FFRDC Transfer	-	-0.024	-	-	-

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 / 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 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
812: <i>Mil HIV Vac&Drug Dev</i>	-	1.184	-	-	-	-	-	-	-	-	0.000	1.184
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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 2021	FY 2022	FY 2023
Title: Military HIV Vaccine and Drug Development	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.			
Accomplishments/Planned Programs Subtotals	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 2023 Army												Date: April 2022			
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 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 Management Services Cost	Various	Various : Various	3.677	0.491		-		-		-		-	Continuing	Continuing	-
Subtotal			3.677	0.491		-		-		-		-	Continuing	Continuing	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	Various	Henry M. Jackson Foundation, : Various	33.967	-		-		-		-		-	Continuing	Continuing	Continuing
Subtotal			33.967	-		-		-		-		-	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	Various : Various	2.413	-		-		-		-		-	Continuing	Continuing	-
Regulatory Support	Option/ Various	Clinical Research Management, Inc : Various	0.909	-		-		-		-		-	0.000	0.909	-
Subtotal			3.322	-		-		-		-		-	Continuing	Continuing	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	Various	Various : Various	29.484	0.693		-		-		-		-	Continuing	Continuing	Continuing
Subtotal			29.484	0.693		-		-		-		-	Continuing	Continuing	N/A

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

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
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 2023 Army										Date: April 2022		
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 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
832: Field Medical Systems Engineering Development	-	31.244	27.437	5.513	-	5.513	6.598	7.615	7.011	7.078	0.000	92.496
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

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

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

	FY 2021	FY 2022	FY 2023
Title: Field Medical Systems Engineering Development PM Warfighter Protection and Acute Care Description: Funding is provided for engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including blood products.	9.419	-	-
Title: Field Medical Systems Engineering Development PM Warfighter Health, Performance and Evacuation (formerly PM Medical Support Systems) Description: This project funds the engineering and manufacturing development of medical products for prevention of injury, enhanced combat casualty care, and evacuation.	11.308	-	-
Title: Field Medical Systems Engineering Development - PM Warfighter Brain Health Description: This effort funds systems engineering development of medical products for enhanced combat casualty care for diagnosis of Traumatic Brain Injury (TBI).	10.517	-	-
Title: Field Medical Systems Engineering Development - Medical Readiness Description: Funding is provided for engineering and manufacturing development of medical products for diagnostic devices and testing of medical devices for use in the field. FY 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.	-	11.236	5.513

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army		Date: April 2022		
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 2021	FY 2022	FY 2023
<p>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.</p> <p>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 2023 Plans: Laboratory Assay for TBI- Point of Care: 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 0605145DHA, Project Code 375D.</p> <p>Medical Device Prototype Development and Testing (formerly Modernization of medical equipment sets): Continue to provide rapid prototype design; fabrication; evaluation and testing; and fixes for medical and medical support products, components and systems as well as harden COTS products for use in a field environment used to sustain and support the Warfighter. Continue to conduct Developmental Test and Evaluation (DT&E) as required by Army and DoD regulations, consisting of Environmental T&E IAW Mil-STD-810G; Performance Verification Testing; and Competitive Analysis.</p> <p>Airworthiness Certification: Continue tests both developmental and commercial off-the-shelf (COTS) carry-on medical equipment destined for use aboard Army aircraft required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products</p> <p>FY 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 0605145DHA, Project Code 375D.</p>				
<p>Title: Field Medical Systems Engineering Development - Battlefield Care and Return to Fight</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 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>		-	15.346	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Army		Date: April 2022		
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 2021	FY 2022	FY 2023
<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><i>FY 2022 to FY 2023 Increase/Decrease Statement:</i> 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 0605145DHA, Project Code 375D.</p>				
<p><i>Title:</i> SBIR/STTR Tax</p> <p><i>FY 2022 Plans:</i> Funding transferred in accordance with Title 15 USC ?638.</p> <p><i>FY 2022 to FY 2023 Increase/Decrease Statement:</i> Funding transferred in accordance with Title 15 USC ?638.</p>		-	0.855	-
Accomplishments/Planned Programs Subtotals		31.244	27.437	5.513
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 2023 Army												Date: April 2022			
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 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 Management Services Cost	Various	Various : Various	53.652	7.220		2.726		2.122		-		2.122	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology : Frederick MD	0.752	-		0.300		-		-		-	0.000	1.052	-
FY22 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.855		-		-		-	0.000	0.855	-
Subtotal			54.404	7.220		3.881		2.122		-		2.122	Continuing	Continuing	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	Various	Various : Various	10.928	1.968		0.691		1.631		-		1.631	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	7.111	3.804		3.514		-		-		-	0.000	14.429	-
Assay for Traumatic Brain Injury	C/Various	Abbott Laboratories : Chicago, IL	21.643	7.271		6.470		-		-		-	Continuing	Continuing	Continuing
Handheld Ultrasound	Various	TBD : TBD	-	-		1.461		-		-		-	Continuing	Continuing	Continuing
Extremity Injury Repair - Vascular	TBD	Humacyte : Morrisville, NC	-	-		2.541		-		-		-	0.000	2.541	-
Subtotal			39.682	13.043		14.677		1.631		-		1.631	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 Device Prototype Development and Testing	Various	Various : Various	13.677	2.842		-		-		-		-	Continuing	Continuing	Continuing

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Exhibit R-4, RDT&E Schedule Profile: PB 2023 Army		Date: April 2022
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>

Event Name	FY 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
Cryopreserved Platelets (CPP) Phase 2/3 clinical studies	[Blue Bar]				[Blue Bar]																							
Freeze-dried Plasma (FDP) Phase I safety clinical studies	[Blue Bar]				[Blue Bar]																							
Freeze-dried Plasma (FDP) Phase 2 efficacy clinical studies	[Blue Bar]				[Blue Bar]																							
Freeze-dried Plasma (FDP) FDA Submission	[Blue Bar]				[Blue Bar]																							
Freeze-dried Plasma (FDP) Phase 3 FDA Post Marketing					[Blue Bar]																							
Assay for TBI Point of Care Device Clinical Trial (Plasma)	[Blue Bar]				[Blue Bar]																							
Assay for TBI Point of Care Device Clinical Trial (Whole Blood)					[Blue Bar]																							
Extremity Injury Repair - Vascular- Pivotal Study					[Blue Bar]																							
Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing									[Blue Bar]																			
Handheld Ultrasound - Developmental Testing					[Blue Bar]																							

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
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 2/3 clinical studies	3	2017	4	2022
Freeze-dried Plasma (FDP) Phase I safety clinical studies	3	2014	4	2022
Freeze-dried Plasma (FDP) Phase 2 efficacy clinical studies	2	2016	4	2022
Freeze-dried Plasma (FDP) FDA Submission	1	2021	3	2022
Freeze-dried Plasma (FDP) Phase 3 FDA Post Marketing	1	2022	4	2022
Assay for TBI Point of Care Device Clinical Trial (Plasma)	1	2021	4	2021
Assay for TBI Point of Care Device Clinical Trial (Whole Blood)	4	2021	4	2022
Extremity Injury Repair - Vascular- Pivotal Study	1	2022	4	2022
Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing	4	2022	4	2022
Handheld Ultrasound - Developmental Testing	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 / 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>			
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
849: <i>Infec Dis Drug/Vacc Ed</i>	-	15.857	16.963	-	-	-	-	-	-	-	0.000	32.820
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 endemic 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 2021	FY 2022	FY 2023
Title: Infectious Disease Drug and Vaccine Engineering Development	15.857	-	-
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.			
Title: Infectious Disease Drug and Vaccine Engineering Development - Medical Readiness	-	12.329	-
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.			
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.			

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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) 849 / <i>Infec Dis Drug/Vacc Ed</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>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 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 0605145DHA, Project Code 375D.</p>				
<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 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 0605145DHA, Project Code 375D.</p>		-	4.112	-
<p>Title: SBIR/STTR Tax</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>		-	0.522	-
Accomplishments/Planned Programs Subtotals		15.857	16.963	-
C. Other Program Funding Summary (\$ in Millions)				
N/A				
Remarks				

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

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 2023 Army												Date: April 2022			
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 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 Management Services Cost	Various	Various : Various	28.949	3.612		0.500		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	14.342	0.333		1.884		-		-		-	0.000	16.559	-
FY22 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.522		-		-		-	0.000	0.522	-
Subtotal			43.291	3.945		2.906		-		-		-	Continuing	Continuing	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
Rapid Human Diagnostics	Various	Inbios, Inc : Seattle WA	3.443	-		3.684		-		-		-	0.000	7.127	-
CARES ACT	TBD	TBD : TBD	24.417	-		-		-		-		-	0.000	24.417	-
Rapid Human Diagnostics	TBD	Cepheid : California	-	3.055		-		-		-		-	0.000	3.055	-
Subtotal			27.860	3.055		3.684		-		-		-	0.000	34.599	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
Dengue Tetravalent Vaccine	TBD	WRAIR/AFRIMS : Silver Spring MD	2.649	0.791		0.861		-		-		-	0.000	4.301	-
Dengue Tetravalent Vaccine	C/TBD	BioPath : Philippines	6.744	0.911		1.017		-		-		-	0.000	8.672	-
Malaria Prophylactic Drug - Tafenoquine	Various	DVC : Frederick MD	5.385	3.988		3.520		-		-		-	0.000	12.893	-

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

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
Dengue Tetravalent Vaccine (DTV) Clinical Trials	[Redacted]				[Redacted]																							
Rapid Human Diagnostic Additional Panels	[Redacted]				[Redacted]																							
Malaria Prophylactic Drug – Tafenoquine Post FDA Approval Marketing Commitment	[Redacted]				[Redacted]																							
Block 1 HIV Phase 2B Clinical Trial	[Redacted]				[Redacted]																							
Block 1 HIV Phase 3 Efficacy Clinical Trial	[Redacted]				[Redacted]																							
Malaria Treatment Drug – Intravenous Artesunate FDA Post marketing commitment	[Redacted]				[Redacted]																							

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Exhibit R-4A, RDT&E Schedule Details: PB 2023 Army		Date: April 2022
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) Clinical Trials	1	2011	4	2022
Rapid Human Diagnostic Additional Panels	1	2020	4	2022
Malaria Prophylactic Drug ? Tafenoquine Post FDA Approval Marketing Studies	4	2019	4	2022
Block 1 HIV Phase 2B Clinical Trial	1	2017	4	2022
Block 1 HIV Phase 3 Efficacy Clinical Trial	4	2019	4	2022
Malaria Treatment Drug ? Intravenous Artesunate FDA Post marketing commitments	4	2021	4	2022