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Exhibit R-2, RDT&E Budget Item Justification: PB 2024 Army **Date:** March 2023

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 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
Total Program Element	-	43.023	5.513	6.496	-	6.496	7.516	6.930	7.004	7.083	0.000	83.565
832: <i>Field Medical Systems Engineering Development</i>	-	26.582	5.513	6.496	-	6.496	7.516	6.930	7.004	7.083	0.000	67.124
849: <i>Infec Dis Drug/Vacc Ed</i>	-	16.441	-	-	-	-	-	-	-	-	0.000	16.441

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)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Previous President's Budget	44.400	5.513	6.598	-	6.598
Current President's Budget	43.023	5.513	6.496	-	6.496
Total Adjustments	-1.377	0.000	-0.102	-	-0.102
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.377	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	-0.102	-	-0.102

Change Summary Explanation

Decreased funding to support higher Army priorities.

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Army										Date: March 2023		
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>			
COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
832: <i>Field Medical Systems Engineering Development</i>	-	26.582	5.513	6.496	-	6.496	7.516	6.930	7.004	7.083	0.000	67.124
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 2022	FY 2023	FY 2024
Title: Field Medical Systems Engineering Development - Medical Readiness	11.236	5.385	6.496
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 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.			
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.			
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			
FY 2024 Plans:			

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Army		Date: March 2023
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 2022	FY 2023	FY 2024
<p>Medical Device Prototype Development and Testing (formerly Modernization of medical equipment sets): Will continue to provide rapid prototype design; fabrication; evaluation and testing; and fixes for medical and medical support products, components and systems as well as harden commercial products for use in a field environment used to sustain and support the Warfighter. Will continue to conduct Developmental Test and Evaluation (DT&E) as required by Army and DoD regulations, consisting of Environmental T&E IAW Mil-STD-810G; Performance Verification Testing; and Competitive Analysis.</p> <p>Airworthiness Testing: Will continue testing both developmental and commercial carry-on medical equipment destined for use aboard Army aircraft required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products.</p> <p>Medical Health Applications: Transitioned some more advanced applications from 6.4 - 836 to 832. Will finalize Independent Verification and Validation, Cyber Security Assessments, and Operational Assessments of performance optimization decision aid(s) for Soldier environmental exposure data collection; Clinical Practice Guidelines (CPGs) to maintain proficiency and expertise while deployed; and optimizes Soldier cold weather clothing ensemble.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: The increase of funding in FY24 is due to the projected requirements of the Medical Health Applications program.</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>	15.346	-	-
<p>Title: SBIR/STTR</p> <p>FY 2023 Plans: Funding transferred in accordance with Title 15 USC §638.</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Funding transferred in accordance with Title 15 USC §638.</p>	-	0.128	-
Accomplishments/Planned Programs Subtotals	26.582	5.513	6.496

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 2024 Army												Date: March 2023			
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 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	60.872	2.726		2.058		3.299		-		3.299	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology : Frederick MD	0.752	0.300		-		-		-		-	0.000	1.052	-
SBIR/STTR Transfer	Various	Various : Various	-	-		0.128		-		-		-	0.000	0.128	-
Subtotal			61.624	3.026		2.186		3.299		-		3.299	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	12.896	0.691		1.631		0.652		-		0.652	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	10.915	3.514		-		-		-		-	0.000	14.429	-
Assay for Traumatic Brain Injury	C/Various	Abbott Laboratories : Chicago, IL	28.914	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			52.725	14.677		1.631		0.652		-		0.652	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Device Prototype Development and Testing	Various	Various : Various	16.519	-		-		0.106		-		0.106	Continuing	Continuing	Continuing

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2024 Army **Date:** March 2023

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
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Support (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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			
Airworthiness Certification and Evaluation	TBD	Various : Various	2.995	1.813		1.696		1.783		-		1.783	0.000	8.287	-
Medical Health Applications	TBD	Various : Various	-	-		-		0.656		-		0.656	0.000	0.656	-
Subtotal			19.514	1.813		1.696		2.545		-		2.545	Continuing	Continuing	N/A

Test and Evaluation (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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			
Cryopreserved Platelets	C/CPFF	Cellphire : Rockville, MD	17.996	1.246		-		-		-		-	0.000	19.242	-
Freeze Dried Plasma	C/CPFF	Westat : Rockville, MD	18.383	5.820		-		-		-		-	0.000	24.203	-
Subtotal			36.379	7.066		-		-		-		-	0.000	43.445	N/A

Project Cost Totals	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	Cost To Complete	Total Cost	Target Value of Contract
	170.242	26.582	5.513	6.496	-	6.496	Continuing	Continuing	N/A

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2024 Army		Date: March 2023
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 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027				FY 2028			
	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]				[Grey Bar]																							
Freeze-dried Plasma (FDP) Phase I safety clinical studies	[Blue Bar]																											
Freeze-dried Plasma (FDP) Phase 2 efficacy clinical studies	[Blue Bar]																											
Freeze-dried Plasma (FDP) FDA Submission	[Blue Bar]																											
Freeze-dried Plasma (FDP) Phase 3 FDA Post Marketing	[Blue Bar]																											
Assay for TBI Point of Care Device Clinical Trial (Whole...)	[Blue Bar]																											
Extremity Injury Repair - Vascular- Pivotal Study	[Blue Bar]																											
Extremity Injury Repair - Vascular- Environmental Testi...	[Blue Bar]																											
Handheld Ultrasound - Developmental Testing	[Blue Bar]																											
Medical Health Applications													[Blue Bar]															

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Exhibit R-4A, RDT&E Schedule Details: PB 2024 Army		Date: March 2023
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
Medical Health Applications	1	2024	4	2024

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Army **Date:** March 2023

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 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
849: <i>Infec Dis Drug/Vacc Ed</i>	-	16.441	-	-	-	-	-	-	-	-	0.000	16.441
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 2022	FY 2023	FY 2024
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.			
Title: Infectious Disease Drug and Vaccine Engineering Development - Battlefield Care and Return to Fight	4.112	-	-
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			
Accomplishments/Planned Programs Subtotals	16.441	-	-

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 2024 Army												Date: March 2023				
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)								
2040 / 5				PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				849 / Infec Dis Drug/Vacc Ed								
Management Services (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	32.561	0.620		-		-		-		-	Continuing	Continuing	Continuing	
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	14.675	2.191		-		-		-		-	0.000	16.866	-	
Subtotal			47.236	2.811		-		-		-		-	Continuing	Continuing	N/A	
Product Development (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	2.415		-		-		-		-	0.000	5.858	-	
Subtotal			3.443	2.415		-		-		-		-	0.000	5.858	N/A	
Support (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	
Malaria Treatment Drug - Intravenous Artesunate	C/FFP	Amicas, LLC : MD	-	0.747		-		-		-		-	0.000	0.747	-	
Subtotal			-	0.747		-		-		-		-	0.000	0.747	N/A	
Test and Evaluation (\$ in Millions)				FY 2022		FY 2023		FY 2024 Base		FY 2024 OCO		FY 2024 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	3.440	0.883		-		-		-		-	0.000	4.323	-	

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Exhibit R-4, RDT&E Schedule Profile: PB 2024 Army		Date: March 2023
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 2022				FY 2023				FY 2024				FY 2025				FY 2026				FY 2027				FY 2028			
	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																												
Rapid Human Diagnostic Additional Panels																												
Malaria Prophylactic Drug – Tafenoquine Post FDA Approva...																												
Block 1 HIV Phase 2B Clinical Trial																												
Phase 2B Clinical Trial																												
Block 1 HIV Phase 3 Efficacy Clinical Trial																												
Phase 3 Efficacy Clinical Trial																												
Malaria Treatment Drug – Intravenous Artesunate FDA Pos...																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2024 Army		Date: March 2023
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