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**Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040: Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P)	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
Total Program Element	-	38.371	36.975	28.520	-	28.520	37.008	27.659	27.674	28.273	0.000	224.480
808: DoD Drug & Vacc Ad	-	11.511	11.315	10.894	-	10.894	9.995	9.344	9.494	9.709	0.000	72.262
811: Mil HIV Vac&Drug Dev	-	3.595	5.460	5.098	-	5.098	6.267	1.309	1.145	1.145	0.000	24.019
836: Field Medical Systems Advanced Development	-	15.676	14.107	12.226	-	12.226	20.435	17.006	17.035	17.419	0.000	113.904
CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	-	5.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.000
FF4: Counterdrug, DDR, Sys Development & Demonstration	-	2.296	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	2.296
VST: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.293	6.093	0.302	-	0.302	0.311	0.000	0.000	0.000	0.000	6.999

**A. Mission Description and Budget Item Justification**

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

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<b>Appropriation/Budget Activity</b> 2040: <i>Research, Development, Test &amp; Evaluation, Army / BA 4: Advanced Component Development &amp; Prototypes (ACD&amp;P)</i>	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>
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<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>
Previous President's Budget	39.244	31.175	30.785	-	30.785
Current President's Budget	38.371	36.975	28.520	-	28.520
Total Adjustments	-0.873	5.800	-2.265	-	-2.265
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	5.800			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-0.873	-			
• SBIR/STTR Transfer	-	-			
• Adjustments to Budget Years	-	-	-2.265	-	-2.265

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

**Project:** CS4: *MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)*

Congressional Add: *Transport Telemedicine*

Congressional Add Subtotals for Project: CS4

**Project:** VS7: *MEDEVAC Mission Equipment Package (MEP) - Adv Dev*

Congressional Add: *Transport Telemedicine*

Congressional Add Subtotals for Project: VS7

Congressional Add Totals for all Projects

	<b>FY 2019</b>	<b>FY 2020</b>
	5.000	-
	5.000	-
	-	5.800
	-	5.800
	5.000	5.800

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>				<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
808: <i>DoD Drug &amp; Vacc Ad</i>	-	11.511	11.315	10.894	-	10.894	9.995	9.344	9.494	9.709	0.000	72.262
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

**A. Mission Description and Budget Item Justification**

This Project funds development of candidate medical countermeasures for infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/ devices, and studies to determine if insects infected with pathogenic organisms are capable of infecting service members/preventive medicine measures. These funds support human clinical effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works and continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and accelerated recovery time once diagnosed to enhance battlefield readiness. All clinical trials are conducted in accordance with United States (U.S.) Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat of the disease within the Combatant Commands theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development and production). Products from this Project will transition to PE 0604807A/Project 849.

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> DoD Drug and Vaccine Advanced Development	11.511	10.860	10.894
<b>Description:</b> Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention, early diagnosis and accelerated recovery time. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices.			
<b>FY 2020 Plans:</b> Dengue Vaccine Block II - Will continue the clinical development of the dengue human infection model (DHIM), a tool for rapid evaluation of efficacy of dengue vaccines and therapeutics.  Treatment for Resistant Wound Infections: Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant animal models.  Malaria Chemoprophylaxis ?Tafenoquine (formerly Next Generation Malaria Prophylaxis): Will continue the retinal (eye) safety study (3 year study) started in FY 2017. Address any FDA post-marketing approval requirements.			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army	<b>Date:</b> February 2020
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<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2019	FY 2020	FY 2021
<p>Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)) - The dengue assay transitioned to PE 0604807A Project 849 in FY 2019. The chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for chikungunya.</p> <p><b>FY 2021 Plans:</b> Treatment for Resistant Infections ? Antifungal Drug (formerly Treatment for Resistant Infections): Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant animal models.</p> <p>Malaria Prophylactic Drug ? Tafenoquine (TQ) (Formerly Next Generation Malaria Prophylaxis): Achieved Milestone C in FY 2019. Will continue the retinal (eye) safety study. Additional clinical sites were added. Address any FDA post-marketing approval requirements.</p> <p>Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): The dengue assay did not transition to PE 0604807A Project 849 in FY 2019 as expected. The dengue assay will transition in FY 2020. The chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for chikungunya.</p> <p><b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Funding decrease in FY 2021 to progression of product development efforts.</p>			
<p><b>Title:</b> FY 2020 SBIR/STTR Transfer</p> <p><b>Description:</b> Funding transferred in accordance with Title 15 USC ?638</p> <p><b>FY 2020 Plans:</b> Funding transferred in accordance with Title 15 USC ?638</p> <p><b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Funding transferred in accordance with Title 15 USC ?638</p>	-	0.455	-
<b>Accomplishments/Planned Programs Subtotals</b>	11.511	11.315	10.894

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

N/A

**Remarks**

**D. Acquisition Strategy**

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

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> 808 / DoD Drug & Vacc Ad
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<b>Management Services (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	24.045	4.785		0.659		0.300		-		0.300	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology, : Frederick MD	6.988	0.730		0.709		0.700		-		0.700	0.000	9.127	-
FY 2020 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.455		-		-		-	0.000	0.455	-
<b>Subtotal</b>			31.033	5.515		1.823		1.000		-		1.000	Continuing	Continuing	N/A

<b>Product Development (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Cost	Various	Not applicable : Not applicable	33.219	0.467		5.308		-		-		-	Continuing	Continuing	Continuing
Rapid Diagnostic and Detection Devices	C/Various	Inbios, Inc : Seattle WA	-	1.997		2.363		2.786		-		2.786	0.000	7.146	-
Treatment for Resistant Infections - Antifungal Drug	Various	TBD : TBD	-	-		-		1.993		-		1.993	0.000	1.993	-
Next Generation Malaria Drug (D5P)	Various	TBD : TBD	-	-		-		2.716		-		2.716	0.000	2.716	-
Staphylococcus aureus Vaccine	Various	TBD : TBD	-	-		-		1.818		-		1.818	0.000	1.818	-
<b>Subtotal</b>			33.219	2.464		7.671		9.313		-		9.313	Continuing	Continuing	N/A

<b>Support (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Support Cost	Various	Not Applicable : Not applicable	15.721	0.425		0.042		-		-		-	Continuing	Continuing	Continuing



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**Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>
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Event Name	FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025			
	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 Vaccine Block II Human Infection model studies																									FY24-FY28			
Treatment for Resistant Wound Infections Antifungal Drug Phase 2 Safety trial	FY16-FY23																											
D5P Next Generation Malaria Drug Phase 2 Safety trial	FY17-FY25												FY21-FY26															
Rapid Human Diagnostic Devices	FY17-FY25																											

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**Exhibit R-4A, RDT&E Schedule Details:** PB 2021 Army **Date:** February 2020

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

Events	Start		End	
	Quarter	Year	Quarter	Year
Dengue Vaccine Block II Human Infection model studies	1	2025	4	2028
Treatment for Resistant Wound Infections Antifungal Drug Phase 2 safety trial	1	2017	4	2023
D5P Next Generation Malaria Drug Phase 2 Safety trial	4	2021	4	2025
Rapid Human Diagnostic Devices	4	2017	4	2025

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>				<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
811: <i>Mil HIV Vac&amp;Drug Dev</i>	-	3.595	5.460	5.098	-	5.098	6.267	1.309	1.145	1.145	0.000	24.019
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

**A. Mission Description and Budget Item Justification**

This Project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides for the planning and conduct of human clinical trials in a group of healthy volunteers to assess for safety and tolerability of medical countermeasures, how the drug/vaccine is distributed through, metabolized in, and excreted from the body, and to investigate the appropriate dose. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment. The cumulative cost of treating HIV-positive DoD personnel is estimated to be \$16.6 billion for 3000 personnel over a 50-year lifetime. All clinical trials are conducted in accordance with U.S. FDA regulations. Products from this Project will transition to PE 0604807A/Project 812.

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

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> Military HIV Vaccine & Drug Development	3.595	5.212	5.098
<b>Description:</b> This Project funds advanced development research to develop candidate HIV vaccines, assess their safety and effectiveness in evaluations with human subjects, and protect military personnel from risks associated with HIV infection.			
<b>FY 2020 Plans:</b> Regional Vaccine Candidate: Effort will not be funded in this BA until FY 2023 when the effort transitions to advanced development.			
Global Vaccine Candidate: Will continue to support clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.			
<b>FY 2021 Plans:</b> Global Vaccine Candidate: Will continue to support clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.			
<b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> The decrease of funding in FY 2021 was due to the projected requirements of the program.			
<b>Title:</b> FY 2020 SBIR/STTR Transfer	-	0.248	-
<b>Description:</b> Funding transferred in accordance with Title 15 USC ?638			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army	<b>Date:</b> February 2020
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<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b><i>FY 2020 Plans:</i></b> Funding transferred in accordance with Title 15 USC ?638			
<b><i>FY 2020 to FY 2021 Increase/Decrease Statement:</i></b> Funding transferred in accordance with Title 15 USC ?638			
<b>Accomplishments/Planned Programs Subtotals</b>	3.595	5.460	5.098

**C. Other Program Funding Summary (\$ in Millions)**  
N/A

**Remarks**

**D. Acquisition Strategy**  
Test and evaluate commercially developed drug/vaccine candidates in government-managed trials.

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> 811 / Mil HIV Vac&Drug Dev
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<b>Management Services (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Management Services Cost	TBD	Not Applicable : Not Applicable	4.132	-		-		-		-		-	Continuing	Continuing	Continuing
FY 2020 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.248		-		-		-	0.000	0.248	-
<b>Subtotal</b>			4.132	-		0.248		-		-		-	Continuing	Continuing	N/A

**Remarks**  
Not Applicable

<b>Product Development (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Cost	TBD	Not applicable : Not applicable	5.078	-		-		-		-		-	Continuing	Continuing	Continuing
<b>Subtotal</b>			5.078	-		-		-		-		-	Continuing	Continuing	N/A

<b>Support (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Support Cost	TBD	TBD : TBD	3.551	0.990		-		-		-		-	0.000	4.541	-
<b>Subtotal</b>			3.551	0.990		-		-		-		-	0.000	4.541	N/A

**Remarks**  
Not Applicable

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> 811 / Mil HIV Vac&Drug Dev
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Test and Evaluation (\$ in Millions)				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development T&E Cost	TBD	Not applicable : Not Applicable	25.599	2.605		5.212		3.848		-		3.848	0.000	37.264	-
Medical Product Development T&E Cost	C/CPFF	PPD : Wilmington, NC	-	-		-		1.250		-		1.250	0.000	1.250	-
<b>Subtotal</b>			25.599	2.605		5.212		5.098		-		5.098	0.000	38.514	N/A

**Remarks**  
Not Applicable

	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
<b>Project Cost Totals</b>	38.360	3.595	5.460	5.098	-	5.098	Continuing	Continuing	N/A

**Remarks**

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**Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>
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Event Name	FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial																												
Global HIV (Ad26/Ad26+gp140) Phase 3 Efficacy Clinical Trial	FY18-FY21																											
Global HIV (Block 2) Enters TMMR																												
Global HIV (Block 2) Phase 2B Clinical Trial																												

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**Exhibit R-4A, RDT&E Schedule Details:** PB 2021 Army **Date:** February 2020

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

Events	Start		End	
	Quarter	Year	Quarter	Year
Global HIV (Ad26/Ad26+gp140) Enters TMMR	2	2017	3	2017
Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial	1	2019	1	2022
Global HIV (Ad26/Ad26+gp140) Phase 3 Efficacy Clinical Trial	4	2020	1	2025
Global HIV (Block 2) Enters TMMR	2	2024	4	2024
Global HIV (Block 2) Phase 2B Clinical Trial	4	2024	4	2028

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev				<b>Project (Number/Name)</b> 836 / Field Medical Systems Advanced Development			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
836: Field Medical Systems Advanced Development	-	15.676	14.107	12.226	-	12.226	20.435	17.006	17.035	17.419	0.000	113.904
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

**A. Mission Description and Budget Item Justification**

This Project funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This Project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. When available, commercial-off-the-shelf (COTS) medical products are also tested and evaluated for transition to engineering and manufacturing development. Consideration is also given to reducing the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. FDA regulations. Products from this project will transition to PE 0604807A/Project 832.

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> Field Medical Systems Advanced Development - Program Management (PM) Warfighter Expeditionary Medicine and Treatment (formerly PM Medical Devices)	6.947	2.838	11.017
<b>Description:</b> Funding is provided for the development of the following medical devices in support of enhanced combat casualty care.			
<b>FY 2020 Plans:</b> Temporary Corneal Repair (TCR): Continue down-select activities. Initiate pre-clinical segment of the Temporary Corneal Repair contract along with all of the Phase II SBIR?s supporting the TCR contract will be completed.  Extracorporeal Life Support ?Lung/Renal (ECLS ?L/R): Continue clinical trials and device refinement. Conduct MS B review. Post MS B review, down select to most promising device and conduct FDA pre-submission meeting to finalize regulatory strategy.  Non-invasive neuro assessment device (NINAD): Will complete FDA clinical trial. If trial is successful, will initiate manufacturing efforts for NINAD device. Field Anesthesia: Product development eliminated due to CSA priorities.			
<b>FY 2021 Plans:</b> Temporary Corneal Repair: Will conduct initial clinical trials in humans to assess safety. Extracorporeal Life Support - Lung/Renal: Continue pre-clinical and/or clinical studies for the lung and renal components required by the Food and Drug Administration. Non-invasive neuro assessment device (NINAD): Moved to WBH due to PMO Reorganization.			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army		<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
Extremity Injury Repair ? Vascular: Will continue ongoing clinical trials for military relevant applications. Will continue ongoing manufacturing contract.  <b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Increase in funding FY21 is due to reorganization of PMOs.				
<b>Title:</b> Field Medical Systems Advanced Development - PM Warfighter Protection and Acute Care (formerly PM Pharmaceutical Systems)  <b>Description:</b> Funding is provided for development of blood products enhanced combat casualty care and follow-on care.  <b>FY 2020 Plans:</b> Cold Stored Platelets in Platelet Additive Solution: Will begin Phase II clinical trial based on FDA guidance as to patient population (type of injury/surgical procedure) and numbers to assess safety, effectiveness and dose of candidate product. FY 2020 is a planned progression of medical products under development.  <b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Funding decrease in FY 2021 is due to product not requiring funding in FY 2021.		-	4.498	-
<b>Title:</b> Field Medical Systems Advanced Development - PM Warfighter Health, Performance and Evacuation (formerly PM Medical Support Systems)  <b>Description:</b> Funding is provided for the following effort in the development of products that support the medical mission in combat casualty care and health care operations.  <b>FY 2020 Plans:</b> Nett Warrior Enhanced Physiological Sensors (Wearable): Will continue to collaborate with Program Executive Office Soldier on the development of wearable sensors. Will develop a concussion dosimeter which is part of the Integrated Soldier Sensor System.  Semi-autonomous casualty evacuation (CASEVAC) Ground Platform (S-MET): Will be adapting a medical evacuation package to a standardized Army Platform for the transport of a single casualty. Will transition to PE 0604807A Project 832.  Transport Telemedicine Systems (TTS) (Formerly named Operational Virtual Health): The Transport Telemedicine system develops MEDHUB (Medical Hands-free Ultra Wideband Broadcast), which will automatically capture, store, and forward medical data to provide lifesaving situational awareness of patient vitals en-route to the Medical Treatment Facility (MTF). Complete		5.559	4.461	1.209

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army		<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<p>prototype design and operational test for the MEDHUB platform. MEDHUB supports Medical Treatment Facilities (MTF) situational awareness. Continue development of MEDHUB Drug Safety and Tracking peripheral.</p> <p><b>FY 2021 Plans:</b>                      Nett Warrior Enhanced Physiological Sensors (Wearable): Consolidated with, and funded under, Concussion Dosimetry for mTBI Assessment below.</p> <p>Concussion Dosimetry for mTBI Assessment: Prepare sensor and algorithms for validation, verification and operational evaluation or transition to PE 654807 (0604807A)/832.</p> <p>Transport Telemedicine Systems (TTS) (Formerly named Operational Virtual Health): Initiate and complete MEDHUB Increment 1 airworthiness, cyber security and other certifications. Continue development of MEDHUB Increment 2 Drug Safety and Tracking system.</p> <p>Next Generation Uniform Repellent/Impregnation: Project was completed and transitioned to PEO Soldier in FY 2020.</p> <p><b>FY 2020 to FY 2021 Increase/Decrease Statement:</b>                      Funding decrease in FY 2021 is due to reorganization of PMOs.</p>				
<p><b>Title:</b> Field Medical Systems Advanced Development - PM Tissue Injury and Regenerative Medicine</p> <p><b>Description:</b> Funding for engineering and manufacturing development of tissue injury and regenerative medicine health products for enhanced medical capability and readiness</p> <p><b>FY 2020 Plans:</b>                      Field Expedient Large Defect Bone Repair: Will initiate manufacturing of material and pilot efficacy study for repair of damaged or injured bones.</p> <p>Topical Burn Conversion Prevention Product: Continue to prepare for safety and effectiveness trials. Product development efforts will be combined with Systemic Burn Conversion Prevention Product.</p> <p>Systemic Burn Conversion Prevention Product: Continue to prepare for Phase 2 clinical trial. Permanent Acellular Arterial Graft: Depending on FDA guidance at completion of Phase 2, will initiate pivotal study and/or develop trauma registry (database that patients are enrolled in and followed up outside of a randomized clinical trial.</p> <p><b>FY 2020 to FY 2021 Increase/Decrease Statement:</b></p>		-	1.736	-

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army		<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
Funding decrease in FY 2021 due to reorganization of PMOs				
<b>Title:</b> Field Medical Systems Advanced Developmnet - PM Warfighter Brain Health		3.170	-	-
<b>Title:</b> FY 2020 SBIR/STTR Transfer		-	0.574	-
<b>Description:</b> Funding transferred in accordance with Title 15 USC ?638				
<b>FY 2020 Plans:</b> Funding transferred in accordance with Title 15 USC ?638				
<b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Funding transferred in accordance with Title 15 USC ?638				
<b>Accomplishments/Planned Programs Subtotals</b>		15.676	14.107	12.226
<b>C. Other Program Funding Summary (\$ in Millions)</b>				
N/A				
<b>Remarks</b>				
<b>D. Acquisition Strategy</b>				
Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.				

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> 836 / Field Medical Systems Advanced Development
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<b>Management Services (\$ in Millions)</b>				<b>FY 2019</b>		<b>FY 2020</b>		<b>FY 2021 Base</b>		<b>FY 2021 OCO</b>		<b>FY 2021 Total</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>			
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	45.944	1.785		0.924		0.638		-		0.638	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/IDIQ	Not applicable : Not applicable	1.200	1.095		-		-		-		-	0.000	2.295	-
FY 2020 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.574		-		-		-	0.000	0.574	-
<b>Subtotal</b>			47.144	2.880		1.498		0.638		-		0.638	Continuing	Continuing	N/A

<b>Product Development (\$ in Millions)</b>				<b>FY 2019</b>		<b>FY 2020</b>		<b>FY 2021 Base</b>		<b>FY 2021 OCO</b>		<b>FY 2021 Total</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>			
Product Development	TBD	TBD : TBD	0.932	-		-		-		-		-	0.000	0.932	-
Medical Product Development	TBD	ALL Product : Various	3.909	2.811		-		-		-		-	Continuing	Continuing	Continuing
Product Development of Freeze-dried plasma	TBD	TBD : TBD	8.778	-		-		-		-		-	0.000	8.778	-
Point of Care Coagulation Profiler	TBD	TBD : TBD	0.385	-		-		-		-		-	0.000	0.385	-
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	TBD	Banyan BioMarkers, Inc : Alachua FL	15.814	-		-		-		-		-	0.000	15.814	-
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc. : Roseville, MN	3.048	-		-		-		-		-	0.000	3.048	-
Compartment Syndrome Pressure Device	TBD	Twinstar : Minneapolis, MN	1.871	-		-		-		-		-	0.000	1.871	-
Hydration Status Monitor	TBD	Gaia Medical : LaJolla CA	0.841	-		-		-		-		-	0.000	0.841	-

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army												Date: February 2020			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 4				PE 0603807A / Medical Systems - Adv Dev				836 / Field Medical Systems Advanced Development							
Product Development (\$ in Millions)				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 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
Noninvasive Neuromodulator TBI	TBD	TBD : TBD	4.277	-		-		-		-		-	0.000	4.277	-
PTSD	Various	TBD : Various locations	4.275	-		-		-		-		-	0.000	4.275	-
Temporary Corneal Repair	C/Various	Ashvattha Therapeutics, LLC , University of Southern California, Institute of Surgical Research : Redwood City, CA, Los Angeles, CA, San Antonio, TX	5.040	1.795		2.293		4.548		-		4.548	0.000	13.676	-
Extracorporeal Life Support (ECLS) (Formerly ECMO)	Various	Medical Technology Enterprise Consortium : Summerville SC	-	-		-		3.201		-		3.201	0.000	3.201	-
Field Sterilizer	TBD	TBD : TBD	3.515	3.021		-		-		-		-	0.000	6.536	-
Product Development	TBD	HemCon Medical Technologies : Tigard, Oregon	9.720	-		-		-		-		-	10.342	20.062	-
Product Development	TBD	Banyan BioMarkers, Inc : Alachua FL	31.514	-		-		-		-		-	Continuing	Continuing	Continuing
Non-invasive neuro assessment device (NINAD)	C/Various	TBD : TBD	0.800	-		-		-		-		-	0.000	0.800	-
Cold Stored Platelets in Platelet Additive Solution (CSP-PAS) (Formerly Advanced Refrigerated Platel	C/Various	TBD : TBD	-	-		4.570		-		-		-	0.000	4.570	-
Transport Telemedicine Systems (TTS) - MEDHUB	TBD	TBD : TBD	-	0.350		1.928		-		-		-	Continuing	Continuing	Continuing

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army												Date: February 2020			
Appropriation/Budget Activity				R-1 Program Element (Number/Name)				Project (Number/Name)							
2040 / 4				PE 0603807A / Medical Systems - Adv Dev				836 / Field Medical Systems Advanced Development							
<b>Product Development (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 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
Platform (Formerly named Operational Virtual Health)															
Extremity Injury Repair (formerly Permanent Acellular Graft)	TBD	SS/CPFF : HumaCyte: Morrisville, NC	-	1.778		0.931		2.695		-		2.695	Continuing	Continuing	Continuing
Nett Warrior Enhanced Physiological Sensors (Wearable)	TBD	Various : Various	-	-		1.081		-		-		-	Continuing	Continuing	Continuing
<b>Subtotal</b>			94.719	9.755		10.803		10.444		-		10.444	Continuing	Continuing	N/A
<b>Support (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Not Applicable : Not applicable	47.012	2.429		1.128		1.144		-		1.144	Continuing	Continuing	Continuing
<b>Subtotal</b>			47.012	2.429		1.128		1.144		-		1.144	Continuing	Continuing	N/A
<b>Remarks</b>															
No product/contract costs greater than \$1M individually.															
<b>Test and Evaluation (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 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	TBD	Not applicable : Not applicable	38.664	0.612		0.678		-		-		-	Continuing	Continuing	Continuing
<b>Subtotal</b>			38.664	0.612		0.678		-		-		-	Continuing	Continuing	N/A
<b>Remarks</b>															
No product/contract costs greater than \$1M individually.															

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<b>Exhibit R-3, RDT&amp;E Project Cost Analysis:</b> PB 2021 Army								<b>Date:</b> February 2020				
<b>Appropriation/Budget Activity</b> 2040 / 4				<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>				<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>				
	<b>Prior Years</b>	<b>FY 2019</b>		<b>FY 2020</b>		<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>		<b>FY 2021 Total</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
<b>Project Cost Totals</b>	227.539	15.676		14.107		12.226		-	12.226	Continuing	Continuing	N/A

**Remarks**



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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2021 Army		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Temporary Corneal Repair	2	2016	1	2023
Temporary Corneal Repair -Prototype Testing	2	2018	1	2020
Temporary Corneal Repair- Clinical Study	1	2021	4	2022
Noninvasive Neuro Assessment Device development (NINAD)	1	2018	1	2025
Cold Stored Platelets in Platelet Additive solution	4	2017	4	2023
Transport Telemedicine Systems (TTS)- MEDHUB Platform	3	2013	3	2020
Transport Telemedicine Systems (TTS)- MEDHUB Drug Safety and Tracking	4	2017	3	2024
Extremity Injury Repair (Per. Acellular Arterial Graft) - Vascular Pivotal Study	1	2019	1	2021
Permanent Acellular Arterial Graft - Vascular MS B	2	2021	2	2021
Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing	1	2021	1	2022
Extracorporeal Life Support- Developmental Contract	4	2020	4	2021

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**Exhibit R-2A, RDT&E Project Justification:** PB 2021 Army **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> CS4 / <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i>
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COST (\$ in Millions)	Prior Years	FY 2019	FY 2020	FY 2021 Base	FY 2021 OCO	FY 2021 Total	FY 2022	FY 2023	FY 2024	FY 2025	Cost To Complete	Total Cost
CS4: <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i>	-	5.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.000
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-	-	-

**A. Mission Description and Budget Item Justification**

Congressional Interest Item funding for medical systems advanced development initiatives in Transport Telemedicine - Initiate Joint Advanced Technology Demonstration for MEDHUB to provide Medical Treatment Facility (MTF) automatic situational awareness system to identify patients en-route to MTFs and automate paramedic tasks.

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

	FY 2019	FY 2020
<b><i>Congressional Add:</i></b> Transport Telemedicine	5.000	-
<b><i>FY 2019 Accomplishments:</i></b> Transport Telemedicine		
<b>Congressional Adds Subtotals</b>	5.000	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A



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<b>Exhibit R-4, RDT&amp;E Schedule Profile: PB 2021 Army</b>			<b>Date: February 2020</b>		
<b>Appropriation/Budget Activity</b> 2040 / 4		<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>		<b>Project (Number/Name)</b> CS4 / <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i>	

Event Name	FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025			
	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
Telemedicine product development (MEDHUB) - Develop MEDHUB prototype																												
Telemedicine product development (MEDHUB) - Peripheral Interface Development																												
Telemedicine product development (MEDHUB) - Software Development																												

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2021 Army		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> CS4 / <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Telemedicine product development (MEDHUB) - Develop MEDHUB Prototype	2	2018	1	2019
Telemedicine product development (MEDHUB) - Peripheral Integration	1	2018	1	2019
Telemedicine product development (MEDHUB) - Software Development	1	2018	1	2019

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>				<b>Project (Number/Name)</b> FF4 / <i>Counterdrug, DDR, Sys Development &amp; Demonstration</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
<i>FF4: Counterdrug, DDR, Sys Development &amp; Demonstration</i>	-	2.296	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	2.296
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

**A. Mission Description and Budget Item Justification**

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

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> Counterdrug, DDR, Sys Development & Demonstration	2.296	-	-
<b>Accomplishments/Planned Programs Subtotals</b>	2.296	-	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A



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<b>Exhibit R-4, RDT&amp;E Schedule Profile: PB 2021 Army</b>		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> FF4 / <i>Counterdrug, DDR, Sys Development &amp; Demonstration</i>

Event Name	FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025			
	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
Coding and Development Testing	[Blue bar]																											
User Testing	[Blue bar]																											

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2021 Army		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> FF4 / <i>Counterdrug, DDR, Sys Development &amp; Demonstration</i>

Schedule Details

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

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army										<b>Date:</b> February 2020		
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev				<b>Project (Number/Name)</b> VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021 Base</b>	<b>FY 2021 OCO</b>	<b>FY 2021 Total</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.293	6.093	0.302	-	0.302	0.311	0.000	0.000	0.000	0.000	6.999
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

**A. Mission Description and Budget Item Justification**

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

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

	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
<b>Title:</b> Medical Evacuation Development	0.293	0.279	0.302
<p><b>Description:</b> This effort involves Aeromedical Evacuation Cabin and Technology Research to determine the optimum space and configuration for performing necessary life-saving paramedic-level tasks. Efforts will develop patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers' lives during point of injury MEDEVAC Missions.</p> <p><b>FY 2020 Plans:</b> Future Vertical Lift (FVL) and UH60 Aeromedical Evacuation Cabin Space and Technology Research and Patient Handling System Design (Medical Evacuation Advanced Development): Continue to develop and design optimum helicopter cabin space configuration and illumination so medics can effectively treat patients during MEDEVAC Missions. Continue to develop patient handling system components and prototypes to ensure paramedics have the ability to perform life-saving tasks in both current and future evacuation platforms. Initiate planning for modernization of the UH60 helicopter medical interior system by reducing weight and designing modularity allowing greater mission flexibility.</p> <p><b>FY 2021 Plans:</b></p>			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2021 Army		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2019</b>	<b>FY 2020</b>	<b>FY 2021</b>
Future Vertical Lift (FVL) Aeromedical Evacuation Patient Handling System Design: Continue to develop and design patient handling system for Future Vertical Lift so medics can effectively treat patients during MEDEVAC Missions. <b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Increase in FY 2021 due to projected requirements of the program.			
<b>Title:</b> FY 2020 SBIR/STTR Transfer <b>Description:</b> Funding transferred in accordance with Title 15 USC ?638 <b>FY 2020 Plans:</b> Funding transferred in accordance with Title 15 USC ?638 <b>FY 2020 to FY 2021 Increase/Decrease Statement:</b> Funding transferred in accordance with Title 15 USC ?638	-	0.014	-
<b>Accomplishments/Planned Programs Subtotals</b>	0.293	0.293	0.302

	<b>FY 2019</b>	<b>FY 2020</b>
<b>Congressional Add:</b> Transport Telemedicine <b>FY 2020 Plans:</b> Transport Telemedicine	-	5.800
<b>Congressional Adds Subtotals</b>	-	5.800

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

N/A

**Remarks**

**D. Acquisition Strategy**

Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC and regulatory requirements for production and fielding.

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army** **Date:** February 2020

<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev	<b>Project (Number/Name)</b> VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev
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<b>Management Services (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 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 Services Cost	Various	APM MEDEVAC PEO Aviation : Huntsville, AL	0.318	0.293		3.054		0.302		-		0.302	0.000	3.967	-
FY 2020 SBIR/STTR Transfer	TBD	Various : Various	-	-		0.014		-		-		-	0.000	0.014	-
<b>Subtotal</b>			0.318	0.293		3.068		0.302		-		0.302	0.000	3.981	N/A

<b>Product Development (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Cost	TBD	APM MEDEVAC PEO Aviation : Huntsville AL	1.624	-		3.025		-		-		-	0.000	4.649	-
<b>Subtotal</b>			1.624	-		3.025		-		-		-	0.000	4.649	N/A

<b>Support (\$ in Millions)</b>				FY 2019		FY 2020		FY 2021 Base		FY 2021 OCO		FY 2021 Total	Cost To Complete	Total Cost	Target Value of Contract
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost			
Medical Product Development Support Cost	TBD	APM MEDEVAC PEO Aviation : Huntsville, AL	0.911	-		-		-		-		-	0.000	0.911	-
<b>Subtotal</b>			0.911	-		-		-		-		-	0.000	0.911	N/A



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<b>Exhibit R-4, RDT&amp;E Schedule Profile: PB 2021 Army</b>			<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>	

Event Name	FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024				FY 2025			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Sp	Research and development																											

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2021 Army		<b>Date:</b> February 2020
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Space and Technology	1	2017	4	2024