Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Army

Date: March 2019

Appropriation/Budget Activity

2040: Research, Development, Test & Evaluation, Army I BA 4: Advanced

Component Development & Prototypes (ACD&P)

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev

COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	-	36.279	39.244	31.175	-	31.175	30.785	35.315	26.491	27.500	0.000	226.789
808: DoD Drug & Vacc Ad	-	13.305	13.988	11.315	-	11.315	11.781	9.329	8.884	9.432	0.000	78.034
811: Mil HIV Vac&Drug Dev	-	5.022	5.289	5.460	-	5.460	5.603	5.973	1.110	1.146	0.000	29.603
836: Field Medical Systems Advanced Development	-	13.678	14.674	14.107	-	14.107	13.099	19.702	16.497	16.922	0.000	108.679
CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	-	0.000	5.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	5.000
FF4: Counterdrug, DDR, Sys Development & Demonstration	-	4.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	4.000
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.274	0.293	0.293	-	0.293	0.302	0.311	0.000	0.000	0.000	1.473

### 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.

PE 0603807A: Medical Systems - Adv Dev

Army

Page 1 of 38

Exhibit R-2, RDT&E Budget Item Justification: PB 2020 A	rmy			Date:	March 2019
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army I BA Component Development & Prototypes (ACD&P)	4: Advanced		ement (Number/Name) Medical Systems - Adv I		
B. Program Change Summary (\$ in Millions)	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total
Previous President's Budget	33.491	34.284	39.477	-	39.477
Current President's Budget	36.279	39.244	31.175	-	31.175
Total Adjustments	2.788	4.960	-8.302	-	-8.302
<ul> <li>Congressional General Reductions</li> </ul>	-0.025	-0.040			
<ul> <li>Congressional Directed Reductions</li> </ul>	-	-			
<ul> <li>Congressional Rescissions</li> </ul>	-	-			
<ul> <li>Congressional Adds</li> </ul>	-	5.000			
<ul> <li>Congressional Directed Transfers</li> </ul>	-	-			
<ul> <li>Reprogrammings</li> </ul>	4.000	-			
SBIR/STTR Transfer	-1.187	-			
<ul> <li>Adjustments to Budget Years</li> </ul>	-	-	-8.302	-	-8.302

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

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

Congressional Add: Transport Telemedicine

	FY 2018	FY 2019
	-	5.000
Congressional Add Subtotals for Project: CS4	-	5.000
Congressional Add Totals for all Projects	-	5.000

# **Change Summary Explanation**

Funding reduced in FY 2020 to support the Army's modernization priorities in support of the National Defense Strategy.

**UNCLASSIFIED** 

PE 0603807A: Medical Systems - Adv Dev Page 2 of 38 Army R-1 Line #86

Exhibit R-2A, RDT&E Project Ju	xhibit R-2A, RDT&E Project Justification: PB 2020 Army												
Appropriation/Budget Activity 2040 / 4			, , , ,					umber/Name) Drug & Vacc Ad					
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost	
808: DoD Drug & Vacc Ad	-	13.305	13.988	11.315	-	11.315	11.781	9.329	8.884	9.432	0.000	78.034	
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)	FY 2018	FY 2019	FY 2020
Title: DoD Drug and Vaccine Advanced Development	13.305	13.511	11.315
<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			
FY 2019 Plans: 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. Proposed solutions could be stand-alone treatments or adjuncts to established medical practice. Candidate treatments could be small-molecule drugs, biologicals such as bacteriophages, or antibodies.			
Next Generation Malaria Prophylaxis: Will continue the retinal (eye) safety study (3 year study) started in FY17. Address any FDA post-marketing approval requirements.			

PE 0603807A: Medical Systems - Adv Dev UNCLASSIFIED

Army Page 3 of 38 R-1 Line #86

	UNCLASSIFIED			
Exhibit R-2A, RDT&E Project Justification: PB 2020 Army			March 2019	
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/ 808 / DoD Drug &		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostic continue to be developed and evaluated. Clinical testing will be conducted.				
FY 2020 Plans: Dengue Vaccine Block II: Will continue the clinical development of the evaluation of efficacy of dengue vaccines and therapeutics.	dengue human infection model (DHIM), a tool for rapid			
Treatment for Resistant Wound Infections: Will monitor technical maturefficacy in relevant animal models.	ity of candidate treatments for evidence of safety and			
Malaria Chemoprophylaxis ?Tafenoquine (formerly Next Generation M study (3 year study) started in FY17. Address any FDA post-marketing		у		
Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostion 0604807A Project 849 in FY19. The chikungunya assays will continue conducted for chikungunya.				
FY 2019 to FY 2020 Increase/Decrease Statement: Funding decrease in FY20 to support the Army's modernization prioritie	es in support of the National Defense Strategy.			
Title: FY19 SBIR/ STTR Transfer		-	0.477	
Description: FY19 SBIR/STTR Transfer				
<b>FY 2019 Plans:</b> FY19 SBIR/STTR Transfer				
FY 2019 to FY 2020 Increase/Decrease Statement: FY19 SBIR/STTR Transfer				
	Accomplishments/Planned Programs Subt	otals 13.305	13.988	11.3

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

N/A

Remarks

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED Page 4 of 38

	UNCLASSIFIED	
Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 808 / DoD Drug & Vacc Ad
D. Acquisition Strategy Test and evaluate in-house and commercially developed product licensure and Environmental Protection Agency registration ensu		
E. Performance Metrics		
N/A		

PE 0603807A: *Medical Systems - Adv Dev* Army

	valant C	ant Amelyain, DD C	000 A		UI	NCLASS	SIFIED					Dete	March 20	240	
Exhibit R-3, RDT&E P Appropriation/Budge 2040 / 4			2020 Army					ement (N Medical S				(Numbe	r/Name)		
Management Service	s (\$ in M	illions)		FY 2	FY 2018		FY 2019		2020 se	FY 20		FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	21.565	2.480		2.411		0.724		-		0.724	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	РО	General Dynamics Information Technology, : Frederick MD	4.579	2.409		2.322		0.774		-		0.774	0.000	10.084	-
		Subtotal	26.144	4.889		4.733		1.498		-		1.498	Continuing	Continuing	N/A
Product Developmen	t (\$ in M	illions)		FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Not applicable : Not applicable	30.466	2.753		-		5.373		-		5.373	Continuing	Continuing	Continuing
Rapid Diagnostic and Detection Devices	C/Various	Inbios, Inc : Seattle WA	-	-		2.051		2.428		-		2.428	0.000	4.479	-
FY19 SBIR/ STTR Transfer	TBD	N/A : N/A	-	-		0.477		-		-		-	0.000	0.477	-
		Subtotal	30.466	2.753		2.528		7.801		-		7.801	Continuing	Continuing	N/A
Support (\$ in Millions	s)			FY 2	2018	FY 2	2019	FY 2 Ba	2020 se		2020 CO	FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Not Applicable : Not applicable	15.721	-		1.020		0.107		-		0.107	Continuing	Continuing	Continuing
		Subtotal	15.721	-		1.020		0.107		-		0.107	Continuing	Continuing	N/A

PE 0603807A: Medical Systems - Adv Dev Army

Page 6 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army

Appropriation/Budget Activity

2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev
808 / DoD Drug & Vacc Ad

Test and Evaluation (	(\$ in Milli	ons)		FY 2	2018	FY 2	2019	FY 2 Ba	2020 ise		2020 CO	FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Not applicable : Not applicable	53.852	2.867		0.548		-		-		-	Continuing	Continuing	Continuing
Dengue Block II	IA	WRAIR and AFRIMS : Silver Spring MD	0.800	0.920		3.209		0.877		-		0.877	0.000	5.806	-
Malaria Prophylaxis clinical trial	TBD	TBD : TBD	7.299	1.876		1.950		1.032		-		1.032	0.000	12.157	-
		Subtotal	61.951	5.663		5.707		1.909		-		1.909	Continuing	Continuing	N/A
		ſ													Target

									Target
	Prior			FY 2	2020 FY	2020 FY 2020	Cost To	Total	Value of
	Years	FY 2018	FY 2	2019 Ba	ise O	CO Total	Complete	Cost	Contract
Project Cost Totals	134.282	13.305	13.988	11.315	-	11.315	Continuing	Continuing	N/A

Remarks

PE 0603807A: *Medical Systems - Adv Dev* Army

Page 7 of 38

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army

Appropriation/Budget Activity
2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev
808 / DoD Drug & Vacc Ad

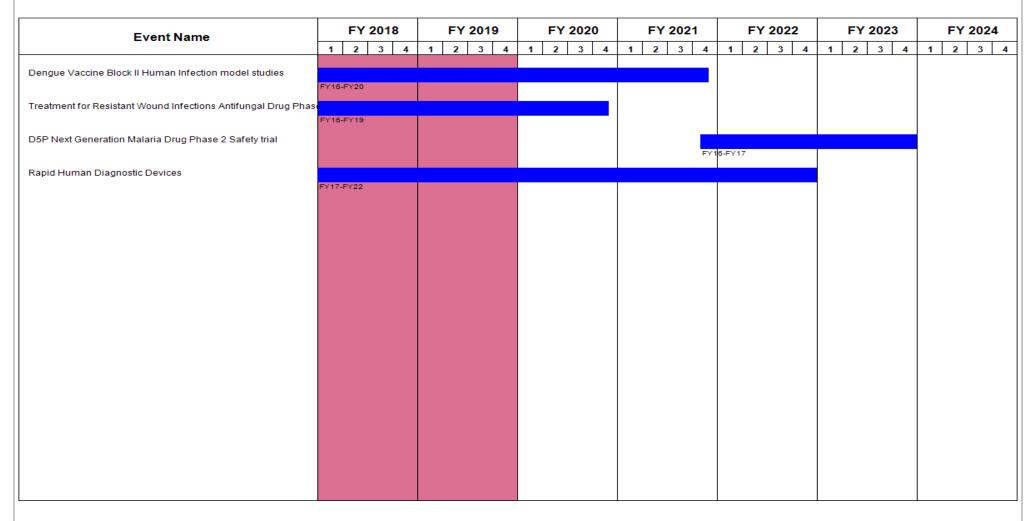


Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (N	umber/Name)
2040 / 4	PE 0603807A I Medical Systems - Adv Dev	808 <i>I DoD</i>	Drug & Vacc Ad

# Schedule Details

	St	art	End		
Events	Quarter	Year	Quarter	Year	
Dengue Vaccine Block II Human Infection model studies	1	2016	4	2021	
Treatment for Resistant Wound Infections Antifungal Drug Phase 2 safety trial	1	2016	4	2020	
D5P Next Generation Malaria Drug Phase 2 Safety trial	4	2021	4	2023	
Rapid Human Diagnostic Devices	4	2017	4	2022	

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army  Date: March 2019												
Appropriation/Budget Activity 2040 / 4	, , , , ,					Number/Name) HIV Vac&Drug Dev						
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
811: Mil HIV Vac&Drug Dev	-	5.022	5.289	5.460	-	5.460	5.603	5.973	1.110	1.146	0.000	29.603
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)	FY 2018	FY 2019	FY 2020
Title: Military HIV Vaccine & Drug Development	5.022	5.095	5.460
<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.			
FY 2019 Plans: New components of the regional vaccine will be tested in FY19. This testing will determine if improved effectiveness can be achieved. This study will be conducted in three regions and is supported by the U.S. Army and DAIDS.			
The cohort studies in Thailand and Germany will be completed in FY19, with results available by the end of the FY. Selection of clinical sites for future effectiveness studies will be initiated.			
FY 2020 Plans: Regional Vaccine Candidate: Effort will not be funded in this BA until FY23 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.			
FY 2019 to FY 2020 Increase/Decrease Statement: The increase of funding in FY20 was due to the inflation factor.			
Title: FY 2019 SBIR/ STTR Transfer	-	0.194	-

PE 0603807A: Medical Systems - Adv Dev

Appropriation/Budget Activity R-1 Program Element (Number/Name) Project (Number/Name)	Date: March 2019
2040 / 4 PE 0603807A / Medical Systems - Adv Dev 811 / Mil HIV Vac&Drug Dev	,

2040 / 4	1 L 0000001AT Wedical Systems - Adv Dev 0111	wiii i ii v vaca	Diag Dev	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Description: FY19 SBIR/STTR Transfer				
FY 2019 Plans: FY19 SBIR/STTR Transfer				
FY 2019 to FY 2020 Increase/Decrease Statement: FY19 SBIR/STTR Transfer				
	Accomplishments/Planned Programs Subtotals	5.022	5.289	5.460

# 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.

# **E. Performance Metrics**

N/A

PE 0603807A: *Medical Systems - Adv Dev* Army

Page 11 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (N	umber/Name)
2040 / 4	PE 0603807A I Medical Systems - Adv Dev	811 <i>I Mil H</i>	IIV Vac&Drug Dev

Management Services (\$ in Millions)		FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	TBD	Not Applicable : Not Applicable	3.280	0.852		-		-		-		-	Continuing	Continuing	Continuing
		Subtotal	3.280	0.852		-		-		-		-	Continuing	Continuing	N/A

#### Remarks

Not Applicable

Product Developmen	it (\$ in M	illions)		FY 2	2018	FY 2	019			FY 2020 Base		FY 2020 OCO		FY 2020 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	Total Cost	Target Value of Contract		
Medical Product Development Cost	TBD	Not applicable : Not applicable	4.081	0.997		-		-		-		-	Continuing	Continuing	Continuing		
FY19 SBIR/STTR Transfer	TBD	N/A : N/A	-	-		0.194		-		-		-	0.000	0.194	-		
		Subtotal	4.081	0.997		0.194		-		-		_	Continuing	Continuing	N/A		

Support (\$ in Millions	Support (\$ in Millions)		FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total				
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	TBD	TBD : TBD	2.439	1.112		-		-		-		-	0.000	3.551	-
		Subtotal	2.439	1.112		-		-		-		-	0.000	3.551	N/A

### Remarks

Not Applicable

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED
Page 12 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army Date: March 2019 Appropriation/Budget Activity R-1 Program Element (Number/Name) Project (Number/Name)

2040 / 4 PE 0603807A I Medical Systems - Adv Dev 811 I Mil HIV Vac&Drug Dev

Test and Evaluation (\$ in Millions)		FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 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	23.538	2.061		5.095		5.460		-		5.460	0.000	36.154	-
		Subtotal	23.538	2.061		5.095		5.460		-		5.460	0.000	36.154	N/A

#### **Remarks**

Not Applicable

	Prior Years	FY 2	018	FY 2	019	FY 2 Ba	FY 2020 OCO	FY 2020 Total	Cost To	Total Cost	Target Value of Contract
Project Cost Totals	33.338	5.022		5.289		5.460	-	5.460	Continuing	Continuing	N/A

Remarks

PE 0603807A: Medical Systems - Adv Dev Army

**UNCLASSIFIED** Page 13 of 38

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army

Appropriation/Budget Activity
2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev
811 / Mil HIV Vac&Drug Dev

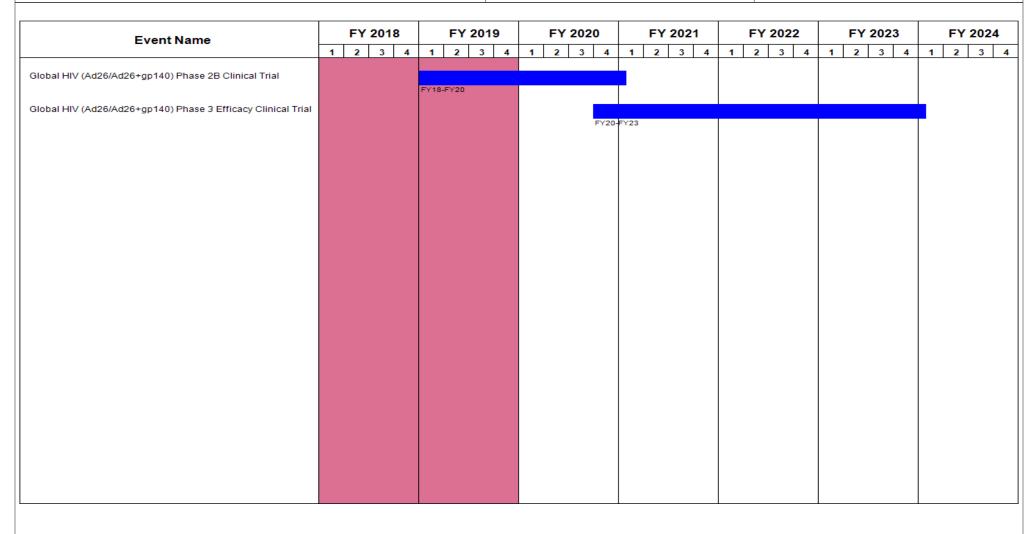


Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (N	umber/Name)
2040 / 4	PE 0603807A I Medical Systems - Adv Dev	811 <i>I Mil H</i>	IIV Vac&Drug Dev

# Schedule Details

	St	art	E	nd
Events	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	2021
Global HIV (Ad26/Ad26+gp140) Phase 3 Efficacy Clinical Trial	4	2020	1	2024

Exhibit R-2A, RDT&E Project Ju	ıstification	: PB 2020 A	rmy							Date: Marc	ch 2019	
Appropriation/Budget Activity 2040 / 4				t (Number/ al Systems	lumber/Name) I Medical Systems Advanced ent							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
836: Field Medical Systems Advanced Development	-	13.678	14.674	14.107	-	14.107	13.099	19.702	16.497	16.922	0.000	108.679
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

### A. Mission Description and Budget Item Justification

PE 0603807A: Medical Systems - Adv Dev

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)	FY 2018	FY 2019	FY 2020
Title: Field Medical Systems Advanced Development - Program Management (PM) Medical Devices	10.991	8.249	2.982
<b>Description:</b> Advanced Concept Development funding is provided for the following development of medical devices in support of enhanced combat casualty care.			
FY 2019 Plans: Field Anesthesia: Will continue clinical trials and prototype comparison.			
Temporary Corneal Repair (TCR): Will continue down select activities.			
Extracorporeal Life Support ? Lung/Renal (formerly Portable ECMO): Will continue clinical trials and device refinement.			
NINAD: Will continue FDA clinical trial for the indication for use of diagnosing mild traumatic brain injury.			
FY 2020 Plans: 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.			

UNCLASSIFIED

Army Page 16 of 38

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: N	larch 2019			
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A I Medical Systems - Adv Dev	Project (Number/Name) 836 I Field Medical Systems Advanced Development				
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020		
Non-invasive neuro assessment device (NINAD): Will complete F efforts for NINAD device. Field Anesthesia: Product development		ng				
FY 2019 to FY 2020 Increase/Decrease Statement: Funding decrease in FY20 to support the Army's modernization p	riorities in support of the National Defense Strategy.					
Title: Field Medical Systems Advanced Development - PM Medic	al Support Systems	2.462	2.556	4.60		
<b>Description:</b> Funding is provided for efforts to develop products health care operations.	that support the medical mission in combat casualty care ar	nd				
FY 2019 Plans: Nett Warrior Enhanced Wearable Sensors: Will continue to collabor of wearable sensors.	orate with Program Executive Office Soldier on the develop	ement				
Semi-autonomous casualty evacuation (CASEVAC) Ground Platt Combat Support Systems on the Ground Mobility Vehicle Infantry		k				
FY 2020 Plans: Nett Warrior Enhanced Physiological Sensors (Wearable): Will cothe development of wearable sensors. Will develop a concussion						
Semi-autonomous casualty evacuation (CASEVAC) Ground Platt a standardized Army Platform for the transport of a single casualt		ge to				
Transport Telemedicine Systems (TTS) (Formerly named Operat develops MEDHUB (Medical Hands-free Ultra Wideband Broadca data to provide lifesaving situational awareness of patient vitals e prototype design and operational test for the MEDHUB platform. awareness. Continue development of MEDHUB Drug Safety and	ast), which will automatically capture, store, and forward me n-route to the Medical Treatment Facility (MTF). Complete MEDHUB supports Medical Treatment Facilities (MTF) situa					
FY 2019 to FY 2020 Increase/Decrease Statement: The increase of funding in FY20 is due to the planned progressio telemedicine.	n of medical products under development including transpo	rt				
Title: Field Medical Systems Advanced Development - PM Tissue	e Injury and Regenerative Medicine	0.225	2.250	1.88		

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED
Page 17 of 38

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army			Date: N	larch 2019	
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A I Medical Systems - Adv Dev	Project (Number/Name) 836 I Field Medical Systems Advance Development			
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
<b>Description:</b> Funding for engineering and manufacturing develor for enhanced medical capability and readiness.	oment of tissue injury and regenerative medicine health pro	ducts			
FY 2019 Plans: Topical Burn Conversion Prevention Product: Will submit an Inve effectiveness trials for a product to prevent superficial burn wound injuries.					
Systemic Burn Conversion Prevention Product: Will initiate manu effectiveness) for a product used as an intravenous treatment in I					
Permanent Acellular Arterial Graft: Will initiate manufacturing of n support vascular grafting for extremity repair and reconstruction.	naterial and a Phase 2 (safety and efficacy) clinical trial to				
<b>FY 2020 Plans:</b> Field Expedient Large Defect Bone Repair: Will initiate manufactuinjured bones.	uring of material and pilot efficacy study for repair of damag	ed or			
Topical Burn Conversion Prevention Product: Continue to prepare will be combined with Systemic Burn Conversion Prevention Product:		fforts			
Systemic Burn Conversion Prevention Product: Continue to prepare Depending on FDA guidance at completion of Phase 2, will initiat patients are enrolled in and followed up outside of a randomized	e pivotal study and/or develop trauma registry (database th				
<b>FY 2019 to FY 2020 Increase/Decrease Statement:</b> Funding decrease in FY20 to support the Army's modernization p	priorities in support of the National Defense Strategy.				
Title: Field Medical Systems Advanced Development - PM Pharm	naceutical Systems		-	1.121	4.64
<b>Description:</b> Funding is provided for engineering and manufactu Manager (PM) Pharmaceuticals for enhanced combat casualty ca		n			
FY 2019 Plans:					

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED
Page 18 of 38

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army			Date: N	larch 2019		
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	_		<b>Name)</b> I Systems Adv	dvanced	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020	
Cold Stored Platelets in Platelet Additive Solution: Will complete studies for effectiveness.	product characterization and labeling information	and				
<b>FY 2020 Plans:</b> Cold Stored Platelets in Platelet Additive Solution: Will begin Phase II clinical (type of injury/surgical procedure) and numbers to assess safety, effective progression of medical products under development.	• • • • • • • • • • • • • • • • • • • •					
FY 2019 to FY 2020 Increase/Decrease Statement: The increase of funding in FY20 is due to the planned progression of medic	al products under development.					
Title: FY 2019 SBIR/ STTR Transfer			-	0.498		
Description: FY19 SBIR/STTR Transfer						
FY 2019 Plans: FY19 SBIR/STTR Transfer						
FY 2019 to FY 2020 Increase/Decrease Statement:						

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

N/A

Remarks

### D. Acquisition Strategy

FY19 SBIR/STTR Transfer

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

# **E. Performance Metrics**

N/A

PE 0603807A: Medical Systems - Adv Dev Army

UNCLASSIFIED

Page 19 of 38 R-1 Line #86

**Accomplishments/Planned Programs Subtotals** 

13.678

14.674

14.107

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army

.....

R-1 Program Element (Number/Name)

Date: March 2019

Appropriation/Budget Activity 2040 / 4

PE 0603807A / Medical Systems - Adv Dev

Project (Number/Name)

Dev 836 I Field Medical Systems Advanced

Development

Management Service	s (\$ in M	illions)		FY 2	2018	FY 2	2019	FY 2 Ba	2020 ise		2020 CO	FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Not Applicable : Not applicable	44.935	1.009		0.974		0.996		-		0.996	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/IDIQ	Not applicable : Not applicable	1.200	-		1.185		-		-		-	0.000	2.385	-
		Subtotal	46.135	1.009		2.159		0.996		-		0.996	Continuing	Continuing	N/A

Product Developmen	nt (\$ in M	illions)		FY 2	018	FY 2	019		2020 ase		2020 CO	FY 2020 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	Total Cost	Target Value of Contract
Product Development	TBD	TBD : TBD	0.932	-		-		-		-		-	0.000	0.932	_
Medical Product Development	TBD	ALL Product : Various	3.014	0.895		2.263		-		-		-	Continuing	Continuing	Continuin
Product Development of Freeze-dried plasma	TBD	TBD : TBD	8.778	-		-		-		-		-	Continuing	Continuing	Continuing
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	2.322	0.726		-		-		-		-	0.000	3.048	-
Compartment Syndrome Pressure Device	TBD	Twinstar : Minniapolis, MN	1.871	-		-		-		-		-	0.000	1.871	-
Hydration Status Monitor	TBD	Gaia Medical : LaJolla CA	0.841	-		-		-		-		-	0.000	0.841	-
Noninvasive Neuromodulator TBI	TBD	TBD : TBD	2.036	2.241		-		-		-		-	0.000	4.277	-

PE 0603807A: Medical Systems - Adv Dev Army

UNCLASSIFIED
Page 20 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army Date: March 2019

Appropriation/Budget Activity R-1 Program Element (Number/Name) Project (Number/Name)

2040 / 4 PE 0603807A / Medical Systems - Adv Dev 836 I Field Medical Systems Advanced

Development

Product Developmen	nt (\$ in Mi	illions)		FY 2	018	FY 2	2019	FY 2 Ba			2020 CO	FY 2020 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	Total Cost	Target Value of Contrac
PTSD	Various	TBD : Various locations	2.032	2.243		-		-		-		-	0.000	4.275	-
Temporary Corneal Repair	Various	TBD : TBD	2.479	2.561		-		2.364		-		2.364	0.000	7.404	-
Field Anesthesia	TBD	TBD : Various	2.568	3.205		1.020		-		-		-	0.000	6.793	-
Field Sterilizer	TBD	TBD : TBD	3.515	-		3.121		-		-		-	0.000	6.636	-
Product Development	TBD	HemCon Medical Technologies : Tigard, Oregon	9.720	-		-		-		-		-	Continuing	Continuing	Continuin
Product Development	TBD	Banyan BioMarkers, Inc : Alachua FL	31.514	-		-		-		-		-	Continuing	Continuing	Continuin
Development of Platelet Derived Hemostatic agent	TBD	Fast Track Drugs & Biologics : Frederick, MD	1.800	-		-		-		-		-	Continuing	Continuing	Continuin
Non-invasive neuro assessment device (NINAD)	C/Various	TBD : TBD	0.800	-		2.874		-		-		-	0.000	3.674	-
Cold Stored Platelets in Platelet Additive Solution (CSP-PAS) (Formerly Advanced Refrigerated Platel	C/Various	TBD : TBD	-	-		0.975		4.641		-		4.641	0.000	5.616	-
Transport Telemedicine Systems (TTS) - MEDHUB Platform (Formerly named Operational Virtual Health)	TBD	TBD : TBD	-	-		-		2.000		-		2.000	Continuing	Continuing	Continuin
Permanent Acellular Graft (formerly Extremity Injury Repair - Vascular Graft)	TBD	SS/CPFF: HumaCyte: Morrisville, NC	-	-		-		1.003		-		1.003	Continuing	Continuing	Continuin
Nett Warrior Enhanced Physiological Sensors (Wearable)	TBD	Various : Various	-	-		-		1.153		-		1.153	Continuing	Continuing	Continuin
FY19 SBIR/ STTR Transfer	TBD	N/A : N/A	-	-		0.498		-		-		-	0.000	0.498	-

PE 0603807A: Medical Systems - Adv Dev Army

Page 21 of 38

Exhibit R-3, RDT&E F Appropriation/Budge			.020 Aiiii	<i>/</i>		R <sub>-</sub> 1 Pro	aram Fla	ment (N	umber/Na	amo)	Project	t (Number	March 20		
2040 / 4	t Activity				PE 0603807A I Medical Systems - Adv Dev							ield Medic		ns Advand	ced
Product Developmer	t (\$ in M	illions)		FY 2	2018	FY 2019		FY 2 Ba	2020 se		2020 CO	FY 2020 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	Total Cost	Target Value of Contrac
		Subtotal	90.421	11.871		10.751		11.161		-		11.161	Continuing	Continuing	N/
Support (\$ in Millions	upport (\$ in Millions)				2018	FY 2	2019	FY 2 Ba	2020 se		2020 CO	FY 2020 Total			
	Contract Method	Doufo maio a	Prior		Award		Award		Award	Cost	Award Date	Cost	Cost To	Total Cost	Target Value of Contract
Cost Category Item	& Type	Performing Activity & Location	Years	Cost	Date	Cost	Date	Cost	Date	CUSI	Date	COSt	Complete		
Cost Category Item  Medical Product Development Support Cost			-	<b>Cost</b> 0.548		<b>Cost</b> 1.152	Date	1.200	Date	-	Date		•	Continuing	Continuin
Medical Product Development Support Cost  Remarks	& Type Various	Activity & Location  Not Applicable : Not applicable  Subtotal	Years				Date		Date		Date	1.200	Continuing	Continuing	
Medical Product Development Support Cost  Remarks No product/contract costs of	& Type Various	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.	<b>Years</b> 46.464	0.548	Date	1.152		1.200 1.200		- - FY 2	2020 CO	1.200	Continuing	_	
Medical Product Development Support Cost  Remarks No product/contract costs of	& Type Various	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.	<b>Years</b> 46.464	0.548	Date	1.152 1.152		1.200 1.200	2020	- - FY 2	2020	1.200 1.200	Continuing	_	Target Value of
Medical Product Development Support Cost  Remarks No product/contract costs g  Test and Evaluation  Cost Category Item  Medical Product	& Type Various  reater than \$ in Milli Contract Method	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.  Ons)	Years 46.464 46.464  Prior	0.548 0.548 FY 2	Date	1.152 1.152 FY 2	2019 Award	1.200 1.200 FY 2 Ba	2020 se	FY 2	2020 CO Award	1.200 1.200 FY 2020 Total	Continuing Continuing Cost To Complete	Continuing	Target Value of Contract
Medical Product Development Support Cost  Remarks No product/contract costs of  Test and Evaluation	& Type Various  reater than \$ in Milli Contract Method & Type	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.  Ons)  Performing Activity & Location  Not applicable : Not	Years  46.464  46.464  Prior Years	0.548 0.548 FY 2	Date	1.152 1.152 FY 2	2019 Award	1.200 1.200 FY 2 Ba	2020 se	FY 2	2020 CO Award	1.200 1.200 FY 2020 Total Cost 0.750	Continuing  Continuing  Cost To  Complete  Continuing	Continuing  Total Cost	Target Value of Contract
Medical Product Development Support Cost  Remarks No product/contract costs of the cost Category Item  Medical Product Development T&E Cost	& Type Various  reater than  \$ in Milli Contract Method & Type TBD	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.  Ons)  Performing Activity & Location  Not applicable : Not applicable  Subtotal	Prior Years 38.414	0.548 0.548 FY 2 Cost 0.250	Date	1.152 1.152 FY 2 Cost 0.612	2019 Award	1.200 1.200 FY 2 Ba Cost 0.750	2020 se	FY 2	2020 CO Award	1.200 1.200 FY 2020 Total Cost 0.750	Continuing  Continuing  Cost To  Complete  Continuing	Total Cost Continuing	Target Value of Contrac
Medical Product Development Support Cost  Remarks No product/contract costs of the cost Category Item  Medical Product Development T&E Cost  Remarks	& Type Various  reater than  \$ in Milli Contract Method & Type TBD	Activity & Location  Not Applicable : Not applicable  Subtotal  \$1M individually.  Ons)  Performing Activity & Location  Not applicable : Not applicable  Subtotal	Prior Years 38.414	0.548 0.548 FY 2 Cost 0.250	Date 2018  Award Date	1.152 1.152 FY 2 Cost 0.612	2019 Award Date	1.200 1.200 FY 2 Ba Cost 0.750 0.750	2020 se Award Date	FY 2 OC Cost	2020 CO Award	1.200 1.200 FY 2020 Total Cost 0.750	Continuing  Continuing  Cost To  Complete  Continuing	Total Cost Continuing	Target Value of Contract

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED Page 22 of 38

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army

Appropriation/Budget Activity
2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev
836 / Field Medical Systems Advanced
Development

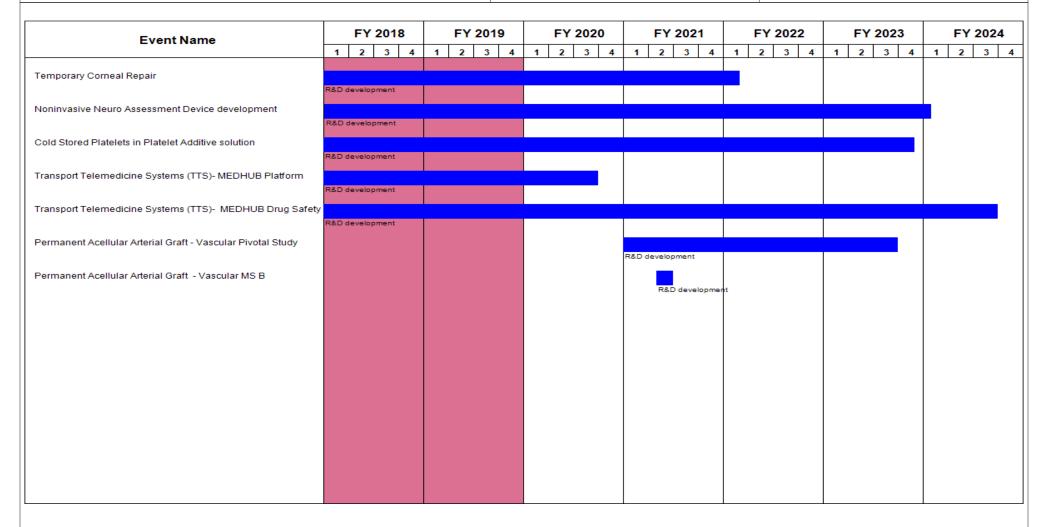


Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
,	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	- , (	_

# Schedule Details

	St	art	E	nd
Events	Quarter	Year	Quarter	Year
Temporary Corneal Repair	2	2016	1	2022
Noninvasive Neuro Assessment Device development	1	2017	1	2024
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
Permanent Acellular Arterial Graft - Vascular Pivotal Study	1	2021	3	2023
Permanent Acellular Arterial Graft - Vascular MS B	2	2021	2	2021

Exhibit R-2A, RDT&E Project Ju	stification	: PB 2020 A	Army							Date: Mare	ch 2019	
Appropriation/Budget Activity 2040 / 4		_	am Elemen 07A / Medica	•	lumber/Name) DICAL SYSTEMS ADV DEV ES (CA)							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	-	0.000	5.000	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 2018	FY 2019
Congressional Add: Transport Telemedicine	-	5.000
FY 2019 Plans: Transport Telemedicine		
Congressional Adds Subtotals	-	5.000

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

N/A

Remarks

# D. Acquisition Strategy

N/A

#### **E. Performance Metrics**

N/A

PE 0603807A: Medical Systems - Adv Dev Army

UNCLASSIFIED
Page 25 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (Number/Name)
2040 / 4	PE 0603807A I Medical Systems - Adv Dev	CS4 I MEDICAL SYSTEMS ADV DEV
		INITIATIVES (CA)

Product Development (\$ in Millions)			FY 2018 FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 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
Telemedicine product development	C/TBD	TBD/: TBD	7.500	-		5.000		-		-		-	0.000	12.500	-
		Subtotal	7.500	-		5.000		-		-		-	0.000	12.500	N/A
															Target

Prior FY 2020 FY 2020 FY 2020 Value of Cost To Total Complete Years FY 2018 FY 2019 Base oco Total Cost Contract 5.000 12.500 **Project Cost Totals** 7.500 0.000 N/A

Remarks

PE 0603807A: Medical Systems - Adv Dev Army

**UNCLASSIFIED** 

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army Date: March 2019

Appropriation/Budget Activity

2040 / 4

R-1 Program Element (Number/Name)

Project (Number/Name) PE 0603807A / Medical Systems - Adv Dev CS4 I MEDICAL SYSTEMS ADV DEV

INITIATIVES (CA)

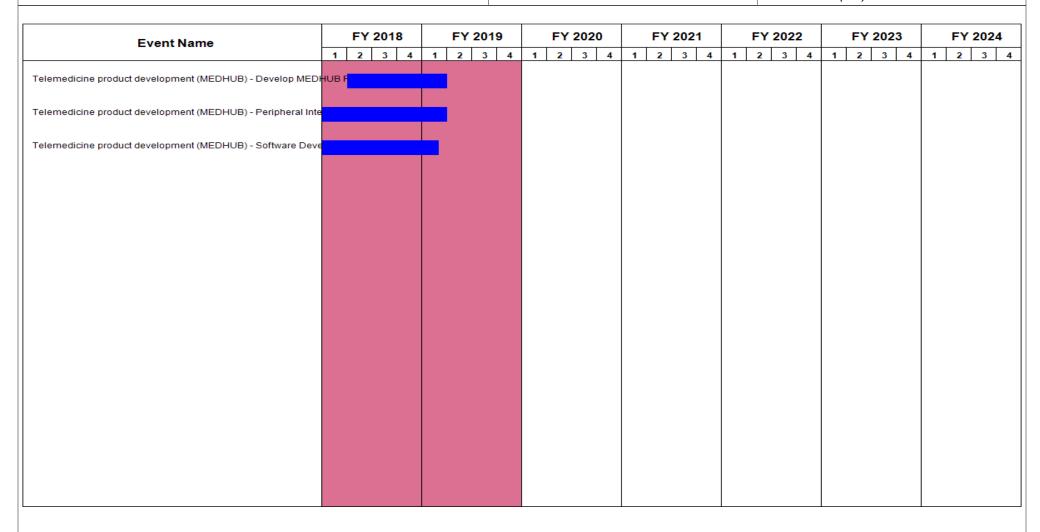


Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
, · · · · · · · · · · · · · · · · · · ·	PE 0603807A I Medical Systems - Adv Dev	- , (	

# Schedule Details

	St	art	End		
Events	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	

Exhibit R-2A, RDT&E Project Ju	stification	: PB 2020 A	rmy						Date: March 2019			
Appropriation/Budget Activity 2040 / 4			_	am Elemen 07A / Medic	•	•	Project (Number/Name) FF4 I Counterdrug, DDR, Sys Development & Demonstration					
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
FF4: Counterdrug, DDR, Sys Development & Demonstration	-	4.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	4.000
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

### A. Mission Description and Budget Item Justification

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
Title: Counterdrug, DDR System Development	4.000	-	-
Accomplishments/Planned Programs Subtotals	4.000	-	-

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

N/A

Remarks

### D. Acquisition Strategy

N/A

### E. Performance Metrics

N/A

Army

PE 0603807A: Medical Systems - Adv Dev

UNCLASSIFIED Page 29 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army		Date: March 2019
, · · · · · · · · · · · · · · · · · · ·	R-1 Program Element (Number/Name) PE 0603807A I Medical Systems - Adv Dev	

Product Developme	nt (\$ in M	illions)		FY 2	2018	FY:	2019		2020 ase		2020 CO	FY 2020 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
Product Development	C/UCA	Alliant Corps LLC : San Antonio, TX	8.400	4.000		-		-		-		-	0.000	12.400	-
		Subtotal	8.400	4.000		-		-		-		-	0.000	12.400	N/A
															Target

													Target
	Prior					FY 2	2020	FY 2	2020	FY 2020	Cost To	Total	Value of
	Years	FY 2	2018	FY 2	2019	Ba	ise	00	CO	Total	Complete	Cost	Contract
Project Cost Totals	8.400	4.000		0.000		-		-		-	0.000	12.400	N/A

Remarks

PE 0603807A: *Medical Systems - Adv Dev* Army

Page 30 of 38

FY 2018 FY 2019 FY 2020 FY 2021 FY 2022 FY 2023 FY 2024 **Event Name** 1 2 3 4 1 2 3 4 1 2 3 4 2 3 4 2 3 4 1 2 3 4 1 1 Coding and Development Testing User Testing

Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
1	PE 0603807A I Medical Systems - Adv Dev	- , (	

# Schedule Details

	St	art	End		
Events	Quarter	Year	Quarter	Year	
Coding and Development Testing	3	2017	1	2019	
User Testing	1	2019	2	2019	

Exhibit R-2A, RDT&E Project Ju	Exhibit R-2A, RDT&E Project Justification: PB 2020 Army													
, · · · · · · · · · · · · · · · · · · ·						am Elemen 07A / Medica	•	VS7 I MÈD	Number/Name) DEVAC Mission Equipment (MEP) - Adv Dev					
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost		
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.274	0.293	0.293	-	0.293	0.302	0.311	0.000	0.000	0.000	1.473		
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-				

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

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

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, model HH-60M. 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. Accomplianments i tumica i regiams (\$ in minions)	1 1 2010	1 1 2019	1 1 2020
Title: Medical Evacuation Development	0.274	0.293	0.293
<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.			
FY 2019 Plans: Future Vertical Lift (FVL) Aeromedical Evacuation Cabin Space and Technology Research and Design (Medical Evacuation Development): Determine optimum space and configuration to perform life-saving paramedic-level tasks in current and future evacuation platforms. Will develop patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers? lives during MEDEVAC Missions.			
FY 2020 Plans: 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			

PE 0603807A: Medical Systems - Adv Dev

FY 2018

FY 2019

FY 2020

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: N	March 2019	
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/ VS7 / MEDEVAC / Package (MEP) - /	Mission Equip	ment
B. Accomplishments/Planned Programs (\$ in Millions)		EV 2019	EV 2010	EV 2020

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2018	FY 2019	FY 2020
modernization of the UH60 helicopter medical interior system by reducing weight and designing modularity allowing greater mission flexibility.			
Accomplishments/Planned Programs Subtotals	0.274	0.293	0.293

# 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.

# **E. Performance Metrics**

N/A

PE 0603807A: Medical Systems - Adv Dev Army

Page 34 of 38

					Ui	NCLASS	DIFIED								
Exhibit R-3, RDT&E F	Project C	ost Analysis: PB 2	2020 Army	/								Date:	March 20	19	
<b>Appropriation/Budge</b> 2040 / 4	t Activity	1	•						umber/Na ystems - A		VS7 / M	(Number EDEVAC e (MEP) -	Equipmer	nt	
Management Service	es (\$ in M	lillions)		FY 2	2018	FY 2	019	FY 2 Ba	2020 se		2020 CO	FY 2020 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 o Contrac
Medical Product Development Management Services Cost	TBD	APM MEDEVAC : Huntsville, AL	0.189	0.129		0.293		0.161		-		0.161	0.000	0.772	-
		Subtotal	0.189	0.129		0.293		0.161		-		0.161	0.000	0.772	N/
Product Developmer	nt (\$ in M	illions)		FY 2	2018	FY 2	019	FY 2 Ba			2020 CO	FY 2020 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	Total Cost	Target Value of Contract
Medical Product Development Cost	TBD	APM MEDEVAC PEO Aviation : Huntsville AL	1.479	0.145		-		0.132		-		0.132	0.000	1.756	-
		Subtotal	1.479	0.145		-		0.132		-		0.132	0.000	1.756	N/A
Support (\$ in Millions	s)			FY 2	2018	FY 2	019	FY 2 Ba	2020 se		2020 CO	FY 2020 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 Contrac
Medical Product Development Support Cost	TBD	APM MEDEVAC : Huntsville, AL	0.911	-		-		-		-		-	0.000	0.911	-
	-	Subtotal	0.911	-		-		-		-		-	0.000	0.911	N/
Test and Evaluation	(\$ in Milli	ions)		FY 2	2018	FY 2	019	FY 2 Ba	2020 se		2020 CO	FY 2020 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 Contrac
Medical Product Development T&E Cost	MIPR	APM MEDEVAC PEO Aviation : Huntsville, AL	0.199	-		-		-		-		-	0.000	0.199	-
		Subtotal	0.199	-		-		-		-		-	0.000	0.199	N/A

PE 0603807A: *Medical Systems - Adv Dev* Army

UNCLASSIFIED
Page 35 of 38

Exhibit R-3, RDT&E Project Cost Analysis: PB	2020 Arm	y								Date:	March 20	19			
Appropriation/Budget Activity 2040 / 4						i <b>lement (N</b> Medical S			VS7 / M	ÈDEVAC	umber/Name) EVAC Mission Equipment MEP) - Adv Dev				
	Prior Years FY 2018						FY 2020 FY FY 2019 Base (					Total Cost	Target Value of Contract		
Project Cost Total	2.778	0.274		0.293		0.293		-		0.293	0.000	3.638	N/A		

Remarks

PE 0603807A: *Medical Systems - Adv Dev* Army

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army

Appropriation/Budget Activity

2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems - Adv Dev
PE 0603807A / Medical Systems - Adv Dev
PE 0603807A / Medical Systems - Adv Dev

Event Name	F	FY 2018			FY 2019			FY 2020				F	1	FY 2022					FY 2023				FY 2024				
	1	2 3	4	1	2	3	4	1	2	3	4	1 2	2	3	4	1	2	3	4	1	2	3	4	1	2	3	3
ture Vertical Lift (FVL) and UH60 Aeromedical Evac Ca	hin Sn																										
ture vertical Lift (FVL) and OHOO Aeromedical Evac Ca		h and deve	elopme	nt																							

Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (N	umber/Name)
2040 / 4	PE 0603807A I Medical Systems - Adv Dev	VS7 I MED	DEVAC Mission Equipment
		Package (I	MEP) - Adv Dev

# Schedule Details

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