

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army DATE: April 2013

APPROPRIATION/BUDGET ACTIVITY					R-1 ITEM NOMENCLATURE							
2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)					PE 0603807A: Medical Systems - Adv Dev							
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	-	34.809	24.384	15.603	-	15.603	30.796	28.442	25.763	25.015	Continuing	Continuing
808: DoD Drug & Vacc Ad	-	11.970	9.987	6.892	-	6.892	13.652	15.008	14.353	13.292	Continuing	Continuing
811: Mil HIV Vac&Drug Dev	-	2.273	2.294	0.550	-	0.550	1.096	0.987	0.859	1.023	Continuing	Continuing
836: Field Medical Systems Advanced Development	-	19.003	11.638	7.599	-	7.599	15.591	12.447	10.551	10.700	Continuing	Continuing
VST: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	1.563	0.465	0.562	-	0.562	0.457	0.000	0.000	0.000	Continuing	Continuing

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

Note

FY14 adjustment was due to higher priorities in DoD.

A. Mission Description and Budget Item Justification

This program element (PE) funds development of medical materiel at the start of an official program of record, within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 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 (F2) requirements stressed within concept documents and organizational structures. The PE 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. The Projects supported by this PE are:

(PROJ 836) funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project also funds the human clinical trials that test the safety and effectiveness of biologics, devices and demonstration. Clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations. Products from this project will transition to 832.

(PROJ 808) funds development of candidate medical countermeasures for infectious diseases of military relevance. Efforts include vaccines, drugs, diagnostic kits/ devices, and insect control measures. These funds support human clinical efficacy trials of the drug/vaccine in a larger group that are designed to assess performance and to continue safety assessments in a larger group of volunteers. Products from this project will transition to 849.

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Army **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY

2040: *Research, Development, Test & Evaluation, Army*
BA 4: *Advanced Component Development & Prototypes (ACD&P)*

R-1 ITEM NOMENCLATURE

PE 0603807A: *Medical Systems - Adv Dev*

(PROJ 811) funds the development of military relevant human immunodeficiency virus (HIV) medical countermeasures. It provides funding for planning and conducting of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and investigate the appropriate dose for therapeutic use. Products from this project will transition to Project 812.

(PROJ VS7) program upgrades, retrofits, trains, and sustains the 256 Medical Evacuation legacy helicopters that continue to play a major role in Iraq and Afghanistan. The force design will increase the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operation needs. Products from this project will transition to VS8.

This program is managed by U.S. Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the US Army Medical Research and Materiel Command.

B. Program Change Summary (\$ in Millions)	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014 Base</u>	<u>FY 2014 OCO</u>	<u>FY 2014 Total</u>
Previous President's Budget	35.543	24.384	20.818	-	20.818
Current President's Budget	34.809	24.384	15.603	-	15.603
Total Adjustments	-0.734	0.000	-5.215	-	-5.215
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.734	-			
• Adjustments to Budget Years	-	-	-5.215	-	-5.215

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>					R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>				PROJECT 808: <i>DoD Drug & Vacc Ad</i>			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
808: <i>DoD Drug & Vacc Ad</i>	-	11.970	9.987	6.892	-	6.892	13.652	15.008	14.353	13.292	Continuing	Continuing
Quantity of RDT&E Articles												
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012 ^{##} The FY 2014 OCO Request will be submitted at a later date												
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 determining if insects are infected with pathogenic organisms 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 to 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 speeding recovery once diagnosed; to enhance battlefield readiness. All clinical trials are conducted in accordance with 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).												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)									FY 2012	FY 2013	FY 2014	
Title: DoD Drug and Vaccine Advanced Development Articles:									11.970 0	9.987 0	6.892	
Description: Funding is provided for the following effort in the development of candidate medical countermeasures for military relevant infectious disease. FY 2012 Accomplishments: Reviewed evaluations, and human clinical trials of malarial/anti-malarial drugs, vaccines, diagnostics, insect repellents, and grouped infectious disease (Dengue [a severe debilitating disease caused by a virus and transmitted by a mosquito] and Leishmania [a skin-based disease caused by a parasite and transmitted by sand flies]) vaccines, drugs and diagnostics. Sought industry partner and evaluated and completed down-selection of drug candidates for human trials for prevention or treatment of malaria. Continued to evaluate the vaccine candidate for Dengue with industry partner Sanofi Pasteur. For Topical												

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 808: <i>DoD Drug & Vacc Ad</i>	
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
Antileishmanial Cream, continued a human treatment protocol in the US, the industry partner continued stability testing of the drug product, and project 849 supported the overseas human clinical trials activities of the topical cream.			
<i>FY 2013 Plans:</i> The New Standard Military Insect Repellent testing transitioned to advanced development in FY 2011, to be funded with Defense Health Program Budget Activity 7 funding as the potential candidates are all commercially available. Will review evaluations, and data from the Phase 2 safety/effectiveness clinical trials completed in FY 2012 for the Topical Antileishmanial Cream; complete preparation for Phase 3 Pivotal clinical trials for Topical Antileishmanial Cream; continue site development efforts in Cambodia and begin a Phase 3 Pivotal clinical trial for Malaria Prophylaxis with commercial partner Glaxo-Smith Kline; finalize analysis and evaluation of Phase 2 effectiveness and safety data for the vaccine candidate for Dengue with industry partner Sanofi Pasteur; transition JBAIDS assay planned to advanced development and begin developmental testing; complete final process validation for Leishmania Rapid Diagnostic Device (LRDD); complete FDA approval and transition to Project 849 for Antimalarial Drug, Artesunate Intravenous.			
<i>FY 2014 Plans:</i> Topical Antileishmanial Cream: will complete site development efforts for Phase 3 New World pivotal safety and effectiveness clinical trial on a diverse population. Malaria Prophylaxis Drug: will complete site development efforts in Cambodia for and initiate Phase 3 (Safety and Effectiveness Clinical Trials on 250 to 3000 subjects) pivotal clinical trials with commercial partner Glaxo-Smith Kline . Tetravalent Dengue Vaccine: will continue volunteer follow up and subsequent analysis of data from pivotal Phase 3 (safety and effectiveness clinical trials on 250 to 3000 subjects) endemic region studies of Tetravalent Dengue Vaccine with commercial partner Sanofi Pasteur , who will provide Go/No Go decision for pursuit of compressed vaccination schedule for US traveler/military indication. Joint Biological Agent identification and Diagnostic System (JBAIDS): An updated Analysis of Alternatives (AoA) and requirements analysis helped to determine that The Dengue JBAIDS capability does not meet user needs; therefore, the project has been terminated. Leishmania Rapid Diagnostic Device (LRDD): Will transition LRDD to Project 849 after completing analytical testing and Good Manufacturing Practices manufacturing runs. Preventive Medicine Products: Preventive medicine products for the control/mitigation of arthropod (insect) borne diseases field testing and evaluation will be delayed for several product candidates to include: field deployable detection devices for Chikungunya, Rift Valley Fever, Sand Fly Fever, Crimean-Congo Fever, advanced arthropod collection devices, Saliva Capture RTA card, spatial repellents, and advanced pesticides based on decrement due to poor disbursements in FY2012. Infectious Disease Diagnostic products field testing and evaluation will be delayed for several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever based on decrement due to poor disbursements in FY2012.			
Accomplishments/Planned Programs Subtotals		11.970	9.987
			6.892

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 808: <i>DoD Drug & Vacc Ad</i>
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and Environmental Protection Agency registration.		
E. Performance Metrics Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.		

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)						R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev						PROJECT 808: DoD Drug & Vacc Ad			
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Not Applicable:Not applicable	12.062	1.470		1.919		1.939		-		1.939	Continuing	Continuing	Continuing
Subtotal			12.062	1.470		1.919		1.939		0.000		1.939			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Not applicable:Not applicable	12.509	8.269		3.080		2.070		-		2.070	Continuing	Continuing	Continuing
Product Development of Malaria Prophylaxis	Various	Walter Reed Army Institute of Research:Silver Spring, MD	0.000	-		3.000		-		-		-	0.000	3.000	0.000
Product Development of Malaria Prophylaxis	Allot	Armed Forces Research Institute of Medical Sciences:Cambodia	0.000	-		-		2.111		-		2.111	0.000	2.111	0.000
Subtotal			12.509	8.269		6.080		4.181		0.000		4.181			
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	6.385	1.431		1.388		0.448		-		0.448	Continuing	Continuing	Continuing
Subtotal			6.385	1.431		1.388		0.448		0.000		0.448			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>							R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>				PROJECT 808: <i>DoD Drug & Vacc Ad</i>			

Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Not applicable:Not applicable	43.318	0.800		0.600		0.324		-		0.324	Continuing	Continuing	Continuing
Subtotal			43.318	0.800		0.600		0.324		0.000		0.324			

	All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	74.274	11.970		9.987		6.892		0.000		6.892			

Remarks

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army			DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>			R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>		
			PROJECT 808: <i>DoD Drug & Vacc Ad</i>		

	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	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
Topical Antileishmanial Cream CDR																												
Arthropod Detection Devices - Field Studies																												
Advanced Pesticides - Field Studies																												
Spatial Repellents - Field Studies																												
Arthropod Collection - Field Studies																												

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 808: <i>DoD Drug & Vacc Ad</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Topical Antileishmanial Cream CDR	4	2012	4	2012
Arthropod Detection Devices - Field Studies	4	2013	4	2015
Advanced Pesticides - Field Studies	4	2013	3	2015
Spatial Repellents - Field Studies	2	2014	2	2016
Arthropod Collection - Field Studies	4	2013	2	2014

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)					R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev				PROJECT 811: Mil HIV Vac&Drug Dev			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
811: Mil HIV Vac&Drug Dev	-	2.273	2.294	0.550	-	0.550	1.096	0.987	0.859	1.023	Continuing	Continuing
Quantity of RDT&E Articles												
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012 ^{##} The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification This project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides funding for the planning and conducting of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and to investigate the appropriate dose for therapeutic use. Development efforts are focused on militarily unique needs effecting manning, mobilization, and deployment. The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)										FY 2012	FY 2013	FY 2014
Title: Military HIV Vaccine & Drug Development										2.273	2.294	0.550
Articles:										0	0	
Description: 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 2012 Accomplishments: Performed three inter-related studies to enhance our understanding of precisely how the vaccine strategy used in the 2009 safety/efficacy trial caused vaccine recipients to be protected from infection, including intense laboratory studies using samples from the trial, and commencement of two small clinical vaccine trials to generate data and samples to define what vaccine responses to try to generate for next increment studies.												
FY 2013 Plans: Complete three inter-related previous clinical trials aimed at refining our understanding of immune responses elicited by the increment 1 HIV vaccine strategy. Analyze laboratory interrogation of samples from trial participants.												
FY 2014 Plans: Will continue the three inter-related clinical trials (RV305, RV306, RV328) aimed at refining our understanding of immune responses elicited by the increment 1 HIV regional vaccine strategy. Will analyze laboratory interrogation of samples from trial												

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>		R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 811: <i>Mil HIV Vac&Drug Dev</i>
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
participants. Will refine vaccine administration schedule as well as clinical trial design based on data from clinical trials. Safety and effectiveness clinical trail RV305, will examine the immune responses to secondary boost of increment 1 HIV regional vaccine. Safety and effectiveness clinical trail RV306, will examine the intensive immune monitoring of Prime-Boost Vaccine. Safety and effectiveness clinical trail RV328, will conduct intensive immune monitoring of AIDSVAXB/E alone Regional Vaccine with a large well controlled trial to test immunity of improved vaccine Boost Prime/Boost Regional study to confirm safety and effectiveness in a diverse population. Will adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine effectiveness to initiate in FY14.			
Accomplishments/Planned Programs Subtotals		2.273	2.294
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			
Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army													DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)							R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev					PROJECT 811: Mil HIV Vac&Drug Dev			

Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	TBD	Not Applicable:Not Applicable	1.135	0.362		0.456		0.165		-		0.165	Continuing	Continuing	Continuing
Subtotal			1.135	0.362		0.456		0.165		0.000		0.165			

Remarks Not Applicable															
----------------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	TBD	Not applicable:Not applicable	2.258	0.360		0.574		0.115		-		0.115	Continuing	Continuing	Continuing
Subtotal			2.258	0.360		0.574		0.115		0.000		0.115			

Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	0.493	0.444		0.534		0.101		-		0.101	0.000	1.572	0.000
Subtotal			0.493	0.444		0.534		0.101		0.000		0.101	0.000	1.572	0.000

Remarks Not Applicable															
----------------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>							R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>					PROJECT 811: <i>Mil HIV Vac&Drug Dev</i>			

Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	14.012	1.107		0.730		0.169		-		0.169	0.000	16.018	0.000
Subtotal			14.012	1.107		0.730		0.169		0.000		0.169	0.000	16.018	0.000

Remarks Not Applicable															
----------------------------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

	All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	17.898	2.273		2.294		0.550		0.000		0.550			

Remarks															
----------------	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army															DATE: April 2013														
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>										R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>										PROJECT 811: <i>Mil HIV Vac&Drug Dev</i>									

	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	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
RV305 Immune Responses to Secondary Boost of Regional Vaccine																												
Regional Vaccine Large Well Controlled Large Trial to Test Immunity of Vaccine																												

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 811: <i>Mil HIV Vac&Drug Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
RV305 Immune Responses to Secondary Boost of Regional Vaccine	1	2013	2	2014
Regional Vaccine Large Well Controlled Large Trial to Test Immunity of Vaccine	3	2014	4	2018

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)					R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev				PROJECT 836: Field Medical Systems Advanced Development			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
836: Field Medical Systems Advanced Development	-	19.003	11.638	7.599	-	7.599	15.591	12.447	10.551	10.700	Continuing	Continuing
Quantity of RDT&E Articles												

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

Note

Not applicable for this PE.

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. Food and Drug Administration (FDA) regulations.

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)

	FY 2012	FY 2013	FY 2014
Title: Field Medical Systems Advanced Development - PM Medical Devices	7.658	6.480	7.523
Articles:	0	0	
Description: Advanced Concept Development funding is provided for the following development of medical devices in support of enhanced combat casualty care.			
FY 2012 Accomplishments: Non-invasive Multi-Analyte Monitor: submitted RFP for the use of Infra Red Spectrometry to assess analyte concentration in blood. Hydration Meter: conducted validation testing. Plasma Knife: transitioned product to Project 832. Eye Tracking System for assessing concussions is a traumatic brain injury diagnostic tool that began clinical trial moved to FDA submission. Fibrinogen Bandages: used an antimicrobial irrigation solution to protect blast injury wound sites from bacterial infection. Conducted final review of Good Manufacturing Practice (GMP) for movement forward to FDA submission. Cardiopulmonary Enhancement: conducted multiple collaborative clinical protocols to review arrest and life threatening trauma devices for enhanced treatment.			
FY 2013 Plans: Total Intravenous Anesthesia (TIVA): This product transitioned to Tech Watch in FY 2012 and is not scheduled for further development in FY 2013. Auto Critical Care System (ACCLS): program cancelled as it is no longer a viable product. Urinary			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev	PROJECT 836: Field Medical Systems Advanced Development		
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
Facilitation Device: no further R&D funding required as this is now a commercial product. PEAK Plasmablade: no further R&D funding required as this is now a commercial product. Hydrosurgery System: no further R&D funding required as this is now a commercial product. Non-invasive Multi-Analyte Monitor: submission cancelled because the Small Business innovation Research (SBIR) Product failed to meet future need/requirement. Eye Tracking System for Assessing Concussions (system is a traumatic brain injury diagnostic tool): IPT for Smooth Pursuit Eye Tracking has re-baselined plan in January 2012 for next steps to reach MSB in FY 2013-FY 2014. Fibrinogen Bandages: Phase I clinical trial to begin in FY 2013. No further funding is planned after current contract. Product is a biologic and is transitioning back to S&T. Cardiopulmonary Enhancement: currently there no device requirement identified. Bandits Banyan Biomarkers (now called TBI Diagnostic Assay System _ Increment II and Increment III Handheld): enrollment for clinical trials continued and identify a handheld platform for independent testing in June 2012. Milestone B review scheduled FY 2014 Plans: Eye Tracking System for Assessing Concussions (system is a traumatic brain injury diagnostic tool): will be re-baselined, as a Request for Information (RFI) was submitted in FY12 to reevaluate the most current devices and no Research Development Test Evaluation (RDTE) funds will be needed in FY14. TBI Diagnostic Assay System Increment II Point of Care Device will enter pivotal clinical trial for safety and effectiveness and transition to engineering and manufacturing funding in project 832. Increment III of the TBI Diagnostic Assay System will be delayed and will not reach milestone B (proof of concept) in FY14 based on the maturity of the technology. Impedance Threshold Device for the Treatment of TBI: Current device has a 510(k) (Premarket Notification) clearance for multiple indications. The submission of a new 510(k) is planned to cover the expanded indications for the currently fielded device. Hydration Status Monitor (HSM) will transition from project MM3 6.3 funding to prepare for milestone B (proof of concept) and down-select. The HSM product will accurately detect the hydration status of Soldiers.				
Title: Field Medical Systems Advanced Development - PM Pharmaceuticals Description: Funding is provided for advanced concept development of biologic medical products managed by PM Pharmaceuticals. FY 2012 Accomplishments: Cryopreserved Platelets formerly Platelet Derived Hemostatic Agent (use of cryopreserved platelets for control of severe bleeding): Conducted clinical safety evaluations and good manufacturing practices preliminary validation studies of the product. The Freeze-Dried Plasma Program (hemorrhage treatment candidate): Conducted preliminary clinical evaluations and good manufacturing practices preliminary validation studies. FY 2013 Plans:		Articles: 7.127 0	2.486 0	0.000

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)	R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev	PROJECT 836: Field Medical Systems Advanced Development		
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
Blood Pathogen Reduction/Inactivation transitioned to advanced development in FY 2012, transitioning from Army to be funded with Defense Health Program RDT&E funding; transitioned to Freeze-dried Plasma program to maintain current schedule and avoid delays. Conduct Milestone B decision reviews for both Cryopreserved Platelets and Freeze-Dried Plasma Programs (new high priority from DoD leadership) and transition to Project 832. Accelerated fielding of a FDA-approved Freeze-Dried Plasma was validated in the June 2011 Army Surgeon General's Report by the Blast Injury Task Force. Cryopreserved Platelets: start Phase 2 safety/effectiveness clinical trial in cancer patients with platelet deficiency. Freeze-Dried Plasma program: complete Phase 2 clinical trial of safety and effectiveness through a Cooperative Agreement with industry partner.				
Title: Field Medical systems Advanced Development - PM Integrated Clinical Systems (ICS) Articles: Description: Funding is provided for the following effort for medical products managed by PM ICS. FY 2012 Accomplishments: Conducted final testing of Phase IV of the Remote Diagnostic Access (RDA). Developed a universal security compliant access portal to serve as a standardized compliance wrapper for all vendors, medical technology, and even IT management products that may traverse between the .com and .mil networks. The Milestone Decision Authority (MDA) was scheduled to review the RDA project in 2011 for continuation of development or termination due to commercial availability.		0.888 0	0.000	0.000
Title: Field Medical Systems Advanced Development - PM Medical Support Systems Articles: Description: 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. FY 2012 Accomplishments: Prepared and completed testing of the Treatment Table and Blood Refrigerator prototypes for PM HBCT. Shock and Vibration Litter Isolation project terminated by MDA. Tested new cold chain technologies for MES set inclusion. Prototype evaluation of Quad fold litter, litter straps, and hands-free litter system: Tested new ISO shelter panel and transitioned back into ISO shelter specification for future shelter buys. Tested Trauma Tiered Medical Bag and transitioned to PEO soldier. Continued to finalize soft-walled shelter development for Force Provider modules for use in Combat Support Hospitals. Developed and transitioned prototype Water and Waste Water Management system to Project 832 for further development. FY 2013 Plans: Transition treatment table and blood refrigerator for PM HBCT to Project 832 and continue development. Transition advanced cold chain technologies, trauma tiered medical bag, hoist aeromedical evacuation litter, and quad fold litter to Project 832 and continue development. Transition ISO panel development and Force Provider soft walled module components to 832 to finalize		3.330 0	2.672 0	0.076

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>		R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 836: <i>Field Medical Systems Advanced Development</i>
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
development. Develop prototype for Environmental Sentinel Biomonitor, which transitioned from Science & Technology. Apply funding from Milestone Decision Authority terminated project Shock and Vibration Litter System to a SBIR Phase II product, insecticide impregnated bed net, and acquire data for EPA approval. Collaborate with PEO Combat Support /Combat Support Service Support on development efforts for emerging medical vehicle evacuation variants.			
FY 2014 Plans: Will continue development of the Environmental Sentinel Biomonitor (ESB) and transition to project 832. The ESB will assist preventive medicine personnel certify water capabilities by providing a presumptive screening capability that can rapidly identify toxicity in water. Will continue collaboration with Program Executive Office Combat Support/Combat Support Service (PEO CS/CSS) and Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for emerging medical vehicle evacuation/casualty evacuation (CASEVAC) variants. Medical variants that will be collaborated on with PEO CS/CSS consist of medical shelters, Mine Resistant Ambush Protected (MRAP), Armored Multipurpose Vehicle (AMPV), and Joint Light Tactical Vehicle (JLTV). Will collaborate with PEO GCS on medical variants for the Heavy Brigade Combat Team (HBCT). Will develop prototypes of Vector Tent Traps for testing. The Vector Tent Trap allows researchers to safely conduct vector (insect) surveillance on vectors that are attracted to humans and vector-borne diseases. Will begin the development of the Altitude Readiness Management System (ARMS). ARMS will transition from S&T MM3 funding line. The ARMS product is a handheld sensor and software decision device to plan, monitor, and manage unit altitude illness risk and task performance prediction.			
Accomplishments/Planned Programs Subtotals		19.003	11.638
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 and regulatory requirements for production and fielding.			
E. Performance Metrics Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)						R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev						PROJECT 836: Field Medical Systems Advanced Development			
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Not Applicable:Not applicable	37.279	2.330		0.622		0.024		-		0.024	Continuing	Continuing	Continuing
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	TBD	Banyan BioMarkers, Inc:Alachua FL	0.000	-		-		0.208		-		0.208	0.000	0.208	0.000
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems, Inc:Roseville, MN	0.000	-		-		0.154		-		0.154	0.000	0.154	0.000
Subtotal			37.279	2.330		0.622		0.386		0.000		0.386			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	TBD	Banyan BioMarkers, Inc:Alachua FL	27.000	-		5.050		-		-		-	Continuing	Continuing	Continuing
Product Development	TBD	HemCon Medical Technologies:Tigard, Oregon	1.520	8.200		-		-		-		-	Continuing	Continuing	Continuing
Development of Platelet Derived Hemostatic agent	TBD	Fast Track Drugs & Biologics:Frederick, MD	0.000	1.800		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development	TBD	ALL Product:Various	1.000	0.931		-		-		-		-	Continuing	Continuing	Continuing
Product Development of Freeze-dried plasma	TBD	TBD:TBD	0.000	-		2.400		-		-		-	Continuing	Continuing	Continuing
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	TBD	Banyan BioMarkers, Inc:Alachua FL	0.000	-		-		5.670		-		5.670	0.000	5.670	0.000
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc.:Roseville, MN	0.000	-		-		1.250		-		1.250	0.000	1.250	0.000

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army													DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)							R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev					PROJECT 836: Field Medical Systems Advanced Development			
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Subtotal			29.520	10.931		7.450		6.920		0.000		6.920			
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	41.747	1.052		1.066		0.200		-		0.200	Continuing	Continuing	Continuing
Subtotal			41.747	1.052		1.066		0.200		0.000		0.200			
Remarks No product/contract costs greater than \$1M individually.															
Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	28.778	4.690		2.500		0.093		-		0.093	Continuing	Continuing	Continuing
Subtotal			28.778	4.690		2.500		0.093		0.000		0.093			
Remarks No product/contract costs greater than \$1M individually.															
			All Prior Years	FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			137.324	19.003		11.638		7.599		0.000		7.599			
Remarks															

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army			DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>			R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>		
			PROJECT 836: <i>Field Medical Systems Advanced Development</i>		

	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Cryopreserved Platelets (CPP) Critical Design Review MS-B																												
Freeze-Dried Plasma (FDP) MS-B																												
Environmental Sentinel Biomonitor MS-B																												
Bench-top/POC Biomarker assay for determining exposure to Traumatic Brain Injury																												
Impedance Threshold Device Device for the Treatment of TBI (PreMarket Note.)																												

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT 836: <i>Field Medical Systems Advanced Development</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Cryopreserved Platelets (CPP) Critical Design Review MS-B	4	2013	4	2013
Freeze-Dried Plasma (FDP) MS-B	4	2013	4	2013
Environmental Sentinel Biomonitor MS-B	1	2013	1	2013
Bench-top/POC Biomarker assay for determining exposure to Traumatic Brain Injury	2	2013	2	2013
Impedance Threshold Device Device for the Treatment of TBI (PreMarket Note.)	3	2013	2	2014

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)					R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev				PROJECT VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	1.563	0.465	0.562	-	0.562	0.457	0.000	0.000	0.000	Continuing	Continuing
Quantity of RDT&E Articles												
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
Original models of Army Black Hawk MEDEVAC helicopters continue to play a major role in maintaining high US troop survival rates in Iraq and Afghanistan by evacuating wounded troops in less than one-hour. In 2009 a VCSA-approved force design update increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs. In 2010, the AMEDD accepted life-cycle management of the MEDEVAC MEP from PEO Aviation. In order to achieve required operational capability and enhance commonality across the MEDEVAC fleet, the MEDEVAC MEP program upgrades, retrofits, trains, and sustains the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)										FY 2012	FY 2013	FY 2014
Title: MEDEVAC Mission Sensor Foward Looking Infrared (FLIR)										0.574	0.000	0.000
Articles:										0		
Description: Funding is provided for the following effort in the advanced development of critical components in MEDEVAC MEP.												
FY 2012 Accomplishments:												
MEDEVAC Mission Sensor (MMS) FLIR for UH-60 aircraft. One of the requirements for the UH-60A/L MEDEVAC was a sensor system that assisted the pilots in locating patient pick-up points and assisted them in maintaining situational awareness in night and adverse weather conditions. The MMS was currently being qualified for use on the HH-60M aircraft. This system will be installed on UH-60 aircraft using the proven Sponson-Mount FLIR system, which was currently being used in OEF for the MEDEVAC mission. The funds were developed and tested a Medical Mission Sensor FLIR prototype on the UH-60A/L.												
Title: Environmental Control System for MEDEVAC aircraft										0.459	0.000	0.000
Articles:										0		
Description: Funding is provided for the following effort												
FY 2012 Accomplishments:												

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2014 Army		DATE: April 2013	
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>		R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT VS7: <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
The HH-60A/L/M had an environmental control system to assist in regulating the cabin temperature. This system helped prevent injury and loss of life to patients due to heat stress or hypothermia during transport. The system provided improved crew comfort in extreme environmental conditions, particularly high temperatures. The system utilized the component-qualified 2-Pallet ECS developed for the HH-60M and developed and tested a prototype installation for the UH-60A/L.			
Title: Telemedicine for MEDEVAC aircraft		0.530	0.465
Articles:		0	0
Description: Effort is focused on requirement to provide enroute patient data to treatment facilities.			
FY 2012 Accomplishments: Telemedicine was an ongoing requirement for US Army MEDEVAC, to allow the patient care-giver at point of injury or during transport to access the knowledge and expertise of a more qualified care-giver at a remote location, and to provide patient data to the receiving facility prior to patient arrival, allowing the facility more time to prepare for intensive care patients. The program developed, installed, and tested a telemedicine system for the UH-60A/L family of aircraft.			
FY 2013 Plans: Design, develop, and test telemedicine systems in order to provide medics with state of the art capability to monitor and communicate patient data to ground crews at forward treatment facility			
FY 2014 Plans: Will continue design, development, and testing of the telemedicine systems in order to provide medics with state of the art capability to monitor and communicate patient data to ground crews at forward treatment facility.			
Accomplishments/Planned Programs Subtotals		1.563	0.465
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 Performance metrics used in the preparation of this justification material may be found in the FY 2010 Army Performance Budget Justification Book, dated May 2010.			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 2040: Research, Development, Test & Evaluation, Army BA 4: Advanced Component Development & Prototypes (ACD&P)						R-1 ITEM NOMENCLATURE PE 0603807A: Medical Systems - Adv Dev						PROJECT VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev			
Management Services (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	TBD	APM MEDEVAC:Huntsville, AL	0.000	0.152		0.037		-		-		-	0.000	0.189	0.000
Subtotal			0.000	0.152		0.037		0.000		0.000		0.000	0.000	0.189	0.000
Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	TBD	APM MEDEVAC PEO Aviation:Huntsville AL	0.000	1.112		0.428		-		-		-	0.000	1.540	0.000
Subtotal			0.000	1.112		0.428		0.000		0.000		0.000	0.000	1.540	0.000
Support (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	APM MEDEVAC:Huntsville, AL	0.000	0.100		-		0.562		-		0.562	0.000	0.662	0.000
Subtotal			0.000	0.100		0.000		0.562		0.000		0.562	0.000	0.662	0.000
Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All 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	MIPR	APM MEDEVAC PEO Aviation:Huntsville, AL	0.000	0.199		-		-		-		-	0.000	0.199	0.000

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Army												DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>						R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>				PROJECT VS7: <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>				

Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Subtotal			0.000	0.199		0.000		0.000		0.000		0.000	0.000	0.199	0.000

	All Prior Years	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	0.000	1.563	0.465	0.562	0.000	0.562	0.000	2.590	0.000

Remarks

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2014 Army																DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY								R-1 ITEM NOMENCLATURE								PROJECT			
2040: Research, Development, Test & Evaluation, Army								PE 0603807A: Medical Systems - Adv Dev								VS7: MEDEVAC Mission Equipment			
BA 4: Advanced Component Development & Prototypes (ACD&P)																Package (MEP) - Adv Dev			

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2014 Army			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 2040: <i>Research, Development, Test & Evaluation, Army</i> BA 4: <i>Advanced Component Development & Prototypes (ACD&P)</i>	R-1 ITEM NOMENCLATURE PE 0603807A: <i>Medical Systems - Adv Dev</i>	PROJECT VS7: <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Telemedicine MS B	3	2015	3	2015
Telemedicine MS C	2	2017	2	2017