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Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army I BA 5: System Development & Demonstration (SDD)					R-1 Program Element (Number/Name) PE 0604807A I Medical Materiel/Medical Biological Defense Equipment - Eng Dev							
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
Total Program Element	-	38.712	39.447	30.397	-	30.397	48.304	44.937	43.593	52.884	Continuing	Continuing
812: Mil HIV Vac&Drug Dev	-	3.134	3.900	1.500	-	1.500	5.068	4.848	5.516	5.629	Continuing	Continuing
832: Field Medical Systems Engineering Development	-	19.878	23.037	18.204	-	18.204	27.980	26.604	24.525	32.171	Continuing	Continuing
849: Infec Dis Drug/Vacc Ed	-	13.358	12.510	10.693	-	10.693	14.857	13.371	13.438	15.084	Continuing	Continuing
VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev	-	2.342	-	-	-	-	0.399	0.114	0.114	-	Continuing	Continuing

The FY 2015 OCO Request will be submitted at a later date.

Note

FY13 adjustments attributed to Congressional General Reductions (-59 thousand); SBIR/STTR transfers (-1.166 million); and Sequestration reductions (-3.458 million). FY15 reduction attributed to realignment to other higher priority Army programs.

A. Mission Description and Budget Item Justification

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

(PROJ 812) project funds military relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development focused on military unique needs effecting manning, mobilization, and deployment. Products from this project will normally transition to DoD Health Programs or OPA Funds.

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

(PROJ 849) funds development of candidate medical countermeasures for military relevant infectious diseases. These products fall between four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. FDA approval is a mandatory obligation for all military products

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placed into the hands of medical providers or service members for human use. Products from this project will normally transition to DoD Health Programs or OPA funds.

(PROJ VS8) program receives products that transition from VS7 and funds effort to complete research and development for the MEDEVAC Mission Essential Packages (MEPs) to support 256 Medical Evacuation legacy helicopters. 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.

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)	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO	FY 2015 Total
Previous President's Budget	43.395	39.468	46.553	-	46.553
Current President's Budget	38.712	39.447	30.397	-	30.397
Total Adjustments	-4.683	-0.021	-16.156	-	-16.156
• Congressional General Reductions	-0.059	-0.021			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.166	-			
• Adjustments to Budget Years	-	-	-16.156	-	-16.156
• Other Adjustments	-3.458	-	-	-	-

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Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 812 / Mil HIV Vac&Drug Dev			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
812: Mil HIV Vac&Drug Dev	-	3.134	3.900	1.500	-	1.500	5.068	4.848	5.516	5.629	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
This project funds militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development is focused on militarily unique needs effecting manning, mobilization, and deployment.												
The major contractor is The Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)										FY 2013	FY 2014	FY 2015
Title: Military HIV Vaccine and Drug Development Articles: Description: This project provides funds for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing of vaccines for medical countermeasures to HIV FY 2013 Accomplishments: Refined vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Adjusted plan for increment 1 future efficacy trial planned to begin in late 2014. FY 2014 Plans: Continue to refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine efficacy which initiated mid-2013 future Prime/Boost Regional Phase 3 Study to Confirm Safety and Effectiveness in a Diverse Populaton, planned to begin in early 2018. FY 2015 Plans: Will continue to refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Will continue to adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine efficacy which initiated mid-2013.										3.134	3.900	1.500
										-	-	-
Accomplishments/Planned Programs Subtotals										3.134	3.900	1.500

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C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy Test and evaluate commercially developed vaccine candidates in government-managed trials.		
E. Performance Metrics N/A		

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 812 / Mil HIV Vac&Drug Dev			
Management Services (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	1.339	0.299		0.823		0.173		-		0.173	Continuing	Continuing	-
Subtotal			1.339	0.299		0.823		0.173		-		0.173	-	-	-
Product Development (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Henry M. Jackson Foundation, : Various	30.279	2.047		0.951		0.325		-		0.325	Continuing	Continuing	Continuing
Subtotal			30.279	2.047		0.951		0.325		-		0.325	-	-	-
Support (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	0.626	0.031		0.878		0.302		-		0.302	Continuing	Continuing	-
Subtotal			0.626	0.031		0.878		0.302		-		0.302	-	-	-
Test and Evaluation (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Henry M. Jackson Foundation, : Various	24.390	0.757		1.248		0.700		-		0.700	Continuing	Continuing	Continuing
Subtotal			24.390	0.757		1.248		0.700		-		0.700	-	-	-

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	Prior Years	FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	56.634	3.134		3.900		1.500		-		1.500	-	-	-
Remarks													

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army			Date: March 2014		
Appropriation/Budget Activity 2040 / 5			R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev		
			Project (Number/Name) 812 / Mil HIV Vac&Drug Dev		

	FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018				FY 2019			
	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
Phase 2 study of Vaccine candidates																												
Initiate Phase 3 Study of Vaccine candidates																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 812 / <i>Mil HIV Vac&Drug Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Phase 2 study of Vaccine candidates	1	2014	4	2014
Initiate Phase 3 Study of Vaccine candidates	1	2019	4	2019

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Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
832: Field Medical Systems Engineering Development	-	19.878	23.037	18.204	-	18.204	27.980	26.604	24.525	32.171	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
# The FY 2015 OCO Request will be submitted at a later date.												
A. Mission Description and Budget Item Justification												
This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project funds pivotal (conclusive) human clinical trials or mechanical engineering evaluations for effectiveness of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Mature commercial-off-the-shelf (COTS) medical products are also evaluated for military use. Consideration is also given to reducing the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. This work is frequently completed through a laboratory/contractor team with the contractor obtaining the U.S. Food and Drug Administration (FDA) licensure for sale of the product.												
Major contractors/intra-governmental agencies include: IGR Enterprises,Inc.;Army Medical Department Board Test Center;Se Qual Technologies,Inc.; Enginivity, Inc.;Ultrasound Diagnostics,Inc.;HemCon Medical Technologies,; Cerdak Ltd;Hemerus Medical,LLC; Fast Track Drugs & Biologics,LLC; Integrated Medical Systems,Inc;the National Institutes of Health National Heart, Lung and Blood Institute (NHLBI), and the U.S. Army Aeromedical Research Laboratory, Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation. Other military agencies include Program Executive Office (PEO) Soldier, PEO Combat Service Support (CSS), and Naval Undersea Warfare Center.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)									FY 2013	FY 2014	FY 2015	
Title: Field Medical Systems Engineering Development PM Medical Devices									0.200	0.943	2.984	
									Articles: -	-	-	
Description: This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by PM Medical Devices.												
FY 2013 Accomplishments:												
The Burn Resuscitation Decision Device: Prepared documentation for CPD and MS B/C. This product transitioned to procurement in FY 2013. MS B/C occurred in FY 2013. Oxygen Generator (15 LPM) System: 15LPM draft CDD completed and a request for proposals (RFP) award was received in March 2012. Continued development with a target to field in FY 2015. Replacement for the M-138 Steam Sterilizer: Conducted testing of the device. Began design and development of system in FY 2012 and continued development through FY 2013.												
FY 2014 Plans:												

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)			FY 2013	FY 2014	FY 2015
<p>Oxygen Generator (15 LPM) System: Instead of ARMY only Request for Proposals (RFP cooperated with the Air Force 15 LPM on developmental effort. Army efforts are airworthiness certification for MEDEVAC aircraft and other Army-unique requirements; Air Force has funding to complete the project for their needs. Replacement for the M-138 Steam Sterilizer: Continue planned testing of devices designed and developed in previous years. Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment is selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits (SKO). Modernization also occurred when products are discontinued, new models are available and new technology introduced to meet current standard of patient care. TBI Diagnostic Assay System Increment II Point of Care Device: Candidate product entered pivotal clinical trial and prepare to obtain FDA approval once transition from project 836 is completed.</p> <p>FY 2015 Plans:</p> <p>Oxygen Generator (15 LPM) System: An MOA was developed in FY13 between USAMMA and the USAF to address this joint requirement. At this time no Army funds are projected for this project. Anticipate DHP RDT&E funds to be used in support of the joint requirement. Replacement for the M-138 Steam Sterilizer: In FY13 the sterilizer project has undergone a major shift in contract strategy. Funds will be used to allow a manufacturer to fully develop and achieve FDA approval by the end of FY15. At the end of the contract period, it is fully anticipated that the Army will have a new sterilizer available for fielding. Will move this project through the DOD Acquisition process to accommodate the modernization effort. Medical Equipment Sets COTS Modernization of Life Cycle Equipment: will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment is selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits (SKO). Modernization also occurs if a product will be discontinued, new models will be available and new technology will be developed to meet the users need. TBI Diagnostic Assay System Increment II Point of Care Device: This effort has seen a dramatic realignment of effort and scope away from Banyan Technologies to Abbott Labs. The focus of this effort is to use the current Biomarker technology developed by Banyan and cross-level all known technologies to Abbott Diagnostics. Contracting efforts will be developed to facilitate this path forward. Army currently uses the i-STAT in assemblages. The intent of this effort is to modernize the i-STAT platform to accommodate the new cartridges associated with the TBI Biomarkers. Noninvasive Neurodiagnostics TBI: Noninvasive Neurodiagnostic technologies for TBI is multi-focused program that transitions product from S&T and Commercial Off the Shelf (COTS) products. Efforts to collate all non-invasive technologies into one integrated IPT are currently in place. The 3 technologies currently involved are the Eye- Tracking System, the QEEG and Balance Platforms. Future components of the multi-focused approach will fall under the scope of this line item. Anticipate full-up IPTs with funding allocations designated in FY15. 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. Advanced Wound Dressing: Will conduct comparative studies for the Advanced Wound Care COTS products (in-vivo animal or human studies).</p>					
Title: Field Medical Systems Engineering Development PM Pharmaceuticals			13.506	16.876	10.470

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)			FY 2013	FY 2014	FY 2015
<p>Articles:</p> <p>Description: Funding is provided for engineering and manufacturing development of medical products managed by PM Pharmaceuticals for enhanced combat casualty care and follow-on care, including rehabilitation.</p> <p>FY 2013 Accomplishments: Blood Pathogen Reduction/Inactivation: Transitioned to advanced development in FY 2012 then it transitioned from Army to be funded with Defense Health Program RDT&E funding in FY13. Remaining Army funding transitioned to Freeze-dried Plasma program to maintain schedule and avoid delays. Freeze-Dried Plasma: Finalized Phase 3 test plan and protocols, recruited test sites for Phase 3 Pivotal clinical trial, and continued development of commercially sustainable current Good Manufacturing Practices compliant manufacturing capability. 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: continued validation of current Good Manufacturing Practices manufacturing processes in support of U.S. Food and Drug Administration licensure. Developed Phase 3 clinical testing network and protocols in the event this is required by the U.S. Food and Drug Administration.</p> <p>FY 2014 Plans: Cryopreserved Platelets: Complete Phase 2 safety and effectiveness clinical trial in cancer patients with platelet deficiency and continue development of Phase 3 clinical testing network and protocols, if Phase 3 Pivotal clinical trial is required by the U.S. Food and Drug Administration. Freeze-Dried Plasma Program: continue development and validation of a sustainable current Good Manufacturing Practices manufacturing process in support of U.S. Food and Drug Administration licensure; and initiate Phase 2b expanded safety and effectiveness clinical studies.</p> <p>FY 2015 Plans: Current Freeze Dried Plasma development effort terminated in FY13 with prime systems contractor due to bankruptcy. Schedule revised for new development effort begin in FY14. Will continue Phase 2b safety clinical study. Cryopreserved Platelets schedule will be extended one year due to the FDA requiring an additional safety clinical study. Will begin Phase 2 efficacy clinical trial in cancer patients with platelet deficiency and continue development of Phase 3 clinical testing and protocols for pivotal study.</p>			-	-	-
<p>Title: Field Medical Systems Engineering Development PM Integrated Clinical Systems (ICS)</p> <p>Description: This project funded the engineering and manufacturing development of medical products managed by PM ICS for enhanced combat casualty care and follow-on care, including rehabilitation.</p> <p>FY 2015 Plans: Pre-Hospital Medical Informatics Transport: Will continue with the Integrated System Design work effort in the Engineering and Manufacturing Development Phase of the Defense Acquisition Management System for the Pre-Hospital Medical Informatics</p>			-	-	1.357

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)			FY 2013	FY 2014	FY 2015
Transport System in order to provide medics with state of the art capability to monitor and communicate patient data to deployed medical treatment facilities and medical C2 nodes.					
Title: Field Medical Systems Engineering Development PM Medical Support Systems			6.172	5.218	3.393
Articles:			-	-	-
Description: This project funds the engineering and manufacturing development of medical products managed by PM Medical Support Systems for enhanced combat casualty care and follow-on care, including rehabilitation.					
FY 2013 Accomplishments: Transitioned from Project 836 and collaborate with PM HBCT on final integration/operational testing of the treatment table and blood refrigerator in the future treatment vehicle variant. As part of the medical equipment sets, transitioned cold chain technology, trauma tiered medical bag, water/waste water management system, and quad fold litter from 836 and complete operational evaluation. Continued modernization of medical equipment sets for preventive medicine, air and ground medical evacuation, and fresh water/waste water combat support hospital support. Transitioned ISO panel from 836 and complete operational testing. Transitioned from 836 and completed final operational evaluation of Force Provider CSH. Complete operational/technical testing of Future Medical Shelter System (hard-wall 1-sided and 2-sided shelters) for a materiel procurement decision. Continued collaboration with PEO Combat Service/Combat Service Support on finalization of MRAP medical vehicle evacuation platforms including a redesign of the Casualty Evacuation (CASEVAC) medical equipment set.					
FY 2014 Plans: As part of the medical equipment sets, continue to perform form, fit and function of field medical sink, and continue to evaluate commercial litters and cold chain storage devices. Continue to evaluate modernization efforts and conduct airworthiness testing for medical equipment sets Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package with products covering preventive medicine, air and ground medical evacuation, and fresh water/waste water systems. Complete operational testing of the ISO operating room shelter and finalize Force Provider soft-walled shelter for procurement. 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). Collaborate with PEO GCS on medical variants for the Heavy Brigade Combat Team (HBCT). Complete operational testing of the Environmental Sentinel Biomonitor (ESB) when it transitions from project 836 and conduct a milestone C (Engineering, Manufacturing and Development phase review). The ESB will assist preventative medicine personnel certify water capabilities by providing a presumptive screening capability that can rapidly identify toxicity in water.					
FY 2015 Plans:					

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2013	FY 2014
<p>Modernization of medical equipment sets: As part of the medical equipment sets, will complete form, fit and function of field medical sink, and will continue to evaluate commercial litters, cold chain storage devices and commercial items. Airworthiness Testing: Will continue to evaluate modernization efforts and conduct airworthiness testing for medical equipment sets Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation. PEO Combat Support /Combat Support Service Support: Will continue collaboration with Program Executive Office Combat Support/Combat Service Support (PEO CS/CS&CSS) and Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for emerging medical vehicle evacuation/casualty evacuation (CASEVAC) package. Environmental Sentinel Biomonitor (ESB): Will complete operational testing of the Environmental Sentinel Biomonitor (ESB) and conduct a milestone C (Engineering, Manufacturing and Development phase review). Milestone C start was delayed in FY14 the ESB will assist preventative medicine personnel certify water capabilities by providing a presumptive screening capability that can rapidly identify toxicity in water. Waste Treatment System for the CSH: Will develop Waste Treatment System (WTS) for the CSH. The WTS will render liquid and other fluid medical (biohazard) waste products sterile and otherwise inert to the environment in austere, deployed locations. Current methods do mitigate the risk of contamination, but only reduce the levels of agents left behind; they cannot assure total inactivation of all pathogens or the neutralization of chemical agents. Altitude Readiness Management System (ARMS): Will complete validation/verification of the Altitude Readiness Management System (ARMS). The ARMS product is a handheld sensor and software decision device to plan, monitor, and manage unit altitude illness risk and task performance prediction. Will transition from 836. Improved Vector Trap: Will develop prototypes of the Improved Vector Trap for testing. The Improved Vector Trap is a device which allows for the attraction and subsequent collection of disease-carrying insects for disease risk assessment. Will transition from 836. Portable Vector Identification Workstation: Will begin development of field deployable Vector Identification Workstation to provide situational awareness necessary to prevent/mitigate vector borne threats and associated environmental hazards.</p>			
Accomplishments/Planned Programs Subtotals		19.878	23.037
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			
N/A			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development					
Management Services (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	22.478	2.577		3.903		2.610		-		2.610	Continuing	Continuing	Continuing
Subtotal			22.478	2.577		3.903		2.610		-		2.610	-	-	-
Product Development (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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
Freeze-dried Human Plasma	Various	HemCon Medical Technologies, Inc. : Tigard OR	23.321	3.953		6.715		-		-		-	Continuing	Continuing	Continuing
Hypertonic Saline Dextran	Various	National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI) : Various	15.100	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Cost	Various	Various : Various	3.260	0.250		0.608		1.124		-		1.124	Continuing	Continuing	Continuing
Extended Life Red Blood Cell Product	Various	Hemerus Medical, LLC, : Various	3.140	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	Clinical Research Management, Inc : Hinckley, OH	0.000	-		1.200		1.911		-		1.911	-	3.111	-
Cryopreserved Platelets	Various	Multiple DoD activities and Dartmouth Hitchcock Med Ctr : North Potomac, MD	7.300	7.062		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	0.000	-		1.450		-		-		-	-	1.450	-
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	Various	Banyan BioMarkers, Inc : Alachua, FL	0.000	-		0.373		-		-		-	-	0.373	-

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development					
Product Development (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Noninvasive Neurodiagnostics	TBD	TBD : TBD	0.000	-		-		2.647		-		2.647	-	2.647	-
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc. : Roseville, MN	0.000	-		-		0.335		-		0.335	-	0.335	-
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine)	TBD	TBD : TBD	0.000	-		-		0.950		-		0.950	-	0.950	-
Subtotal			52.121	11.265		10.346		6.967		-		6.967	-	-	-
Support (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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
Regulatory Support	Various	Clinical Research Management, Inc., : Various	5.557	-		-		0.659		-		0.659	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various : Various	4.746	1.108		4.665		-		-		-	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various : Various	0.000	-		0.456		2.349		-		2.349	-	2.805	-
Subtotal			10.303	1.108		5.121		3.008		-		3.008	-	-	-
Test and Evaluation (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	7.696	4.928		2.403		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	TBD	TBD : TBD	0.000	-		1.150		1.743		-		1.743	-	2.893	-

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 832 / Field Medical Systems Engineering Development			
Test and Evaluation (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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 Equipment Sets Development	Various	Various : Various	0.000	-		0.114		1.092		-		1.092	-	1.206	-
Freeze Dried Plasma	C/CPFF	TBD : TBD	0.000	-		-		2.784		-		2.784	-	2.784	-
Subtotal			7.696	4.928		3.667		5.619		-		5.619	-	-	-
			Prior Years	FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			92.598	19.878		23.037		18.204		-		18.204	-	-	-
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army			Date: March 2014		
Appropriation/Budget Activity 2040 / 5			R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev		
			Project (Number/Name) 832 / Field Medical Systems Engineering Development		

	FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018				FY 2019			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies																												
CPP Phase 3 final pivotal clinical studies prior to FDA licensure																												
Freeze-dried Plasma (FDP) Phase 2b safety clinical studies																												
FDP Phase 2 efficacy clinical studies																												
FDP MS-B																												
Environmental Sentinel Biomonitor MS-C Proof of Concept																												
Noninvasive Neurodiagnostics MS-A																												
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine) MS-A																												
Compartment Syndrome Pressure Device MS-A																												
Hydration Status Monitor MS-B																												
Noninvasive Neuromodulator TBI MS-A																												

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Exhibit R-4A, RDT&E Schedule Details: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies	3	2014	3	2016
CPP Phase 3 final pivotal clinical studies prior to FDA licensure	1	2017	4	2019
Freeze-dried Plasma (FDP) Phase 2b safety clinical studies	3	2014	2	2016
FDP Phase 2 efficacy clinical studies	2	2016	2	2018
FDP MS-B	3	2016	3	2016
Environmental Sentinel Biomonitor MS-C Proof of Concept	1	2015	1	2015
Noninvasive Neurodiagnostics MS-A	4	2014	4	2014
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine) MS-A	2	2013	2	2013
Compartment Syndrome Pressure Device MS-A	4	2013	4	2013
Hydration Status Monitor MS-B	4	2015	4	2015
Noninvasive Neuromodulator TBI MS-A	4	2014	4	2014

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed			
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost
849: Infec Dis Drug/Vacc Ed	-	13.358	12.510	10.693	-	10.693	14.857	13.371	13.438	15.084	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

The FY 2015 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 militarily relevant infectious diseases. These products fall within four major areas: vaccines, drugs, diagnostic kits/devices, and determining if insects are infected with pathogenic organisms capable of infecting service members' insect control/preventive medicine measures to limit exposure and disease transmission. It funds research that supports conclusive human clinical trials for large-scale human effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) testing, expanded human safety clinical trials, long-term animal studies, and related manufacturing tests. This work, which is jointly performed by military laboratories, civilian contracted pharmaceutical firms and foreign research partners, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. Medical products approved for human use must successfully complete a series of clinical trials that are required and regulated by the U.S. Food and Drug Administration (FDA). FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. Development priority is based upon four major factors: (1) the extent of the disease within the Combatant Commands' theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development, production, and sustainment). Malaria, dysentery, hepatitis, and Dengue diseases (a severe debilitating disease transmitted by mosquitoes), which are found in Africa Command, Central Command, European Command, Southern Command, and Pacific Command areas are at the top of the infectious diseases requirements list.

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

	FY 2013	FY 2014	FY 2015
Title: Infectious Disease Drug and Vaccine Engineering Development	13.358	12.510	10.693
Articles:	-	-	-
Description: Funding for research and development efforts for Drugs and Vaccines.			
FY 2013 Accomplishments:			
Reviewed and analyzed data from the on-going Adult Indication study begun in FY 2012 with industry partner Sanofi Pasteur and determine a Go/No Go Decision on continued product development for the Dengue Tetravalent Vaccine. Phase 3 clinical effectiveness studies are on-going with industry partner Sanofi Pasteur for the Dengue Tetravalent Vaccine, as well as Phase 3 studies for traveler/military indication. Completed preparation prior to initiating Phase 3 Pivotal clinical trial for Malaria Prophylaxis Drug. For Topical Antileishmanial Cream, complete Phase 2 safety and effectiveness New World clinical trial analysis and complete Phase 3 New World Pivotal clinical trial, and begin New World Treatment Protocol for Phase 3 site(s). The enteric JBAIDS assay transitions to advanced development and clinical trial planning begins. The Dengue Rapid Diagnostic Device (DRDD) (Hand Held Infectious Disease Diagnostics) transitions to advanced development and will be evaluated in a multi-site			

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014	
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i>	
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2013	FY 2014
<p>clinical performance study. Leishmania Rapid Diagnostic Device (LRDD) continued the new world clinical trial started in FY 2012. The Leishmania Skin Test project completed FDA approval and transition to procurement. The Antimalarial Drug, Artesunate Intravenous transitioned from 808 and conducted a MS C review</p> <p>FY 2014 Plans:</p> <p>:Dengue Tetravalent Vaccine (DTV): Continue patient follow up and serology (study of blood serum) and immunology (study of body's immune system) testing to determine persistence of protection for phase 3 (safety and effectiveness Clinical trials on >300 subjects) endemic region studies, continue performance of military-specific needs US adult clinical studies, and continue studies to determine if the vaccine will protect against the disease. Malaria Prophylaxis Drug (drug to prevent from contracting Malaria): continue Pivotal clinical trials and begin efforts to determine if licensing in Austratlia is feasible. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Will complete New World Phase 3 (safety and effectiveness clinical trials > 300 subjects) clinical trial and Treatment Protocol for Phase 3 site(s), and complete Pivotal clinical trials in Tunisia and the U.S. Dengue 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): conduct milestone C (Engineering, Manufacturing and Development phase review) review, obtain FDA approval, and begin fielding. The Leishmania Skin Test (LST) project: The response from the FDA indicating they would only support limited clinical utility and require additional product characterization and additional clinical trial requirements helped to determine that the LST capability does not meet user needs; therefore, the project has been terminated. Antimalarial Drug, Artesunate Intravenous: Plan to obtain FDA approval and begin fielding to prevent deaths from severe or complicated Malaria. Phase 3 (Safety and Effectiveness Clinical trials on 250 to 3000 subjects). Preventive Medicine advanced detection devices: for the control/mitigation of arthropod (insect) borne diseases, begin field testing and evaluation. Preventive Medicine advanced pesticides : will begin field testing and evaluation. Preventive Medicine spatial repellents: will begin field testing and evaluation. Preventive Medicine arthropod collection devices: begin field testing and evaluation. Infectious Disease Diagnostic products: begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever.</p> <p>FY 2015 Plans:</p> <p>Dengue Tetravalent Vaccine: Dengue Tetravalent Vaccine (DTV): will continue patient follow up and will complete Phase 3 pivotal clinical trials and adult/military-specific indication studies. Will continue and complete follow up of Phase 2 military-specific / immunological evaluation study in Syracuse, NY. Development of Biologic License Application (BLA) for US Licensure, development of Final reports, will continue trial-related activities and data analysis. Commercial Partner will validate production of batches at their dedicated manufacturing facility. Next Generation Malaria Prophylaxis: Malaria Prophylaxis Drug (drug to prevent contracting Malaria): will complete New Drug Application (NDA) preparatory work for a supplemental NDA filing with commercial partner Glaxo-Smith Kline after halting activities associated with a phase 3 study that is no longer needed. Topical Antileishmanial Cream: Topical Antileishmanial Cream: Transitioned from project 808 in FY14. Phase 3 New World clinical trial will be completed</p>			

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014	
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i>	
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2013	FY 2014
<p>in FY15 based on additional guidance and requirements from the FDA. Will conduct MS-C decision review and submit New Drug Application to the FDA. Leishmania Rapid Diagnostic Device: Will complete fielding/delivery of Leishmania Rapid Diagnostic Device. Antimalarial Drug, Artesunate Intravenous: Antimalarial Drug, Artesunate Intravenous: conducted MS-C decision review and submitted New Drug Application to the FDA sent in FY14. Planning to obtain FDA approval in FY15 and begin fielding/delivery of Antimalarial Drug, Artesunate Intravenous. Preventive Medicine advanced detection devices: Preventive Medicine advanced detection devices: for the control/mitigation of arthropod (insect) borne diseases, will begin field testing and evaluation. Preventive Medicine advanced pesticides: Preventive Medicine advanced pesticides: will begin field testing and evaluation. Preventive Medicine spatial repellents: Preventive Medicine spatial repellents: will begin field testing and evaluation. Preventive Medicine arthropod collection devices: Preventive Medicine arthropod collection devices: will begin field testing and evaluation. Infectious Disease Diagnostic: Infectious Disease Diagnostic products: will begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever.</p>			
Accomplishments/Planned Programs Subtotals		13.358	12.510
<p>C. Other Program Funding Summary (\$ in Millions) N/A</p> <p>Remarks</p> <p>D. Acquisition Strategy Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.</p> <p>E. Performance Metrics N/A</p>			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed					
Management Services (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	14.489	2.172		2.220		0.265		-		0.265	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	0.000	-		-		1.012		-		1.012	-	1.012	-
Subtotal			14.489	2.172		2.220		1.277		-		1.277	-	-	-
Product Development (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various : Various	24.594	3.621		5.100		1.331		-		1.331	Continuing	Continuing	Continuing
Topical Antileishmanial Drug	TBD	TBD : TBD	0.000	2.400		-		-		-		-	-	2.400	-
Topical Antileishmanial Drug	C/CPFF	Advantar Laboratories, INC : TBD	0.000	-		-		1.355		-		1.355	-	1.355	-
Dengue Tetravalent Vaccine	TBD	TBD : TBD	0.000	-		-		1.525		-		1.525	-	1.525	-
Subtotal			24.594	6.021		5.100		4.211		-		4.211	-	-	-
Support (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	11.943	2.620		2.624		0.690		-		0.690	Continuing	Continuing	Continuing

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed			
Support (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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 Cos	PO	Clinical Research Management, In : Hinckley, OH	0.000	-		-		3.168		-		3.168	-	3.168	-
Subtotal			11.943	2.620		2.624		3.858		-		3.858	-	-	-
Test and Evaluation (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	33.922	2.545		1.182		1.347		-		1.347	Continuing	Continuing	Continuing
Product Development of Dengue Tetravalent Vaccine	Various	TBD : TBD	0.000	-		1.384		-		-		-	-	1.384	-
Subtotal			33.922	2.545		2.566		1.347		-		1.347	-	-	-
			Prior Years	FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			84.948	13.358		12.510		10.693		-		10.693	-	-	-
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army

Date: March 2014

Appropriation/Budget Activity

2040 / 5

R-1 Program Element (Number/Name)

PE 0604807A / Medical Materiel/Medical
Biological Defense Equipment - Eng Dev

Project (Number/Name)

849 / Infec Dis Drug/Vacc Ed

	FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018				FY 2019			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials																												
DTV Phase 2 Adult Traveler / Military Indication Studies																												
DTV Adult Indication Decision																												
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review																												
DTV Biologic Licensing Application (BLA) Submission																												
DTV BLA Approval																												
Malaria Prophylaxis Phase 3 Safety and Effectiveness Pivotal Clinical Trial																												
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase																												
Paromomycin/Gentamicin TLC Phase 3 Safety and Effectiveness Clinical Trial																												
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development																												
Paromomycin/Gentamicin TLC New Drug Application (NDA)																												
Paromomycin/Gentamicin TLC FDA Approval																												
Paromomycin/Gentamicin TLC (Fielding / Delivery)																												
Leishmania Rapid Diagnostic Device (MS-C) Engineering, Manufacturing and Develop																												
Leishmania Rapid Diagnostic Device FDA Clearance																												

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army																Date: March 2014																					
Appropriation/Budget Activity 2040 / 5										R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev								Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed																			
										FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018				FY 2019			
										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
Leishmania Rapid Diagnostic Device (Fielding / Delivery)																																					
Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)																																					
Antimalarial Drug, Artesunate Intravenous FDA Approval																																					
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)																																					

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Exhibit R-4A, RDT&E Schedule Details: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials	1	2011	4	2015
DTV Phase 2 Adult Traveler / Military Indication Studies	2	2012	1	2016
DTV Adult Indication Decision	4	2014	4	2014
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review	4	2016	4	2016
DTV Biologic Licensing Application (BLA) Submission	1	2017	4	2017
DTV BLA Approval	1	2018	1	2018
Malaria Prophylaxis Phase 3 Safety and Effectiveness Pivotal Clinical Trial	1	2013	4	2013
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase	4	2017	4	2017
Paromomycin/Gentamicin TLC Phase 3 Safety and Effectiveness Clinical Trial	3	2011	1	2015
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development	2	2015	2	2015
Paromomycin/Gentamicin TLC New Drug Application (NDA)	4	2015	4	2015
Paromomycin/Gentamicin TLC FDA Approval	4	2016	4	2016
Paromomycin/Gentamicin TLC (Fielding / Delivery)	1	2017	4	2019
Leishmania Rapid Diagnostic Device (MS-C) Engineering, Manufacturing and Develop	1	2014	1	2014
Leishmania Rapid Diagnostic Device FDA Clearance	4	2014	4	2014
Leishmania Rapid Diagnostic Device (Fielding / Delivery)	4	2014	4	2015
Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)	4	2014	4	2014
Antimalarial Drug, Artesunate Intravenous FDA Approval	3	2015	3	2015
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)	3	2015	4	2019

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014																						
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) VS8 / MEDEVAC Mission Equipment Package (MEP) - End Dev																							
COST (\$ in Millions)	Prior Years	FY 2013	FY 2014	FY 2015 Base	FY 2015 OCO #	FY 2015 Total	FY 2016	FY 2017	FY 2018	FY 2019	Cost To Complete	Total Cost																				
VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev	-	2.342	-	-	-	-	0.399	0.114	0.114	-	Continuing	Continuing																				
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-																						
<p># The FY 2015 OCO Request will be submitted at a later date.</p> <p>A. Mission Description and Budget Item Justification</p> <p>Funding for this project starts in FY 2013. 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 Army Medical Department (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 and retrofits the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.</p> <p>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</p> <table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td></td> <td align="center">FY 2013</td> <td align="center">FY 2014</td> <td align="center">FY 2015</td> </tr> <tr> <td>Title: MEDEVAC Mission Sensor Forward Looking Infrared Radar (FLIR)</td> <td align="right">2.342</td> <td align="center">-</td> <td align="center">-</td> </tr> <tr> <td align="right">Articles:</td> <td align="center">-</td> <td align="center">-</td> <td align="center">-</td> </tr> <tr> <td colspan="4"> <p>Description: MEDEVAC Mission Sensor (MMS) FLIR for UH-60 aircraft. One of the requirements for the UH-60A/L MEDEVAC is a sensor system that will assist the pilots in locating patient pick-up points and assist them in maintaining situational awareness in night and adverse weather conditions. The MMS is 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 is currently being used in Operation Enduring Freedom (OEF) for the MEDEVAC mission.</p> <p>FY 2013 Accomplishments:</p> <p>Transitioned from VS7 and completed testing and integration of the Talon FLIR into the aircraft suspension to ensure maximum capability of the sensor, while minimizing impact to aircraft performance.</p> </td> </tr> <tr> <td align="right">Accomplishments/Planned Programs Subtotals</td> <td align="right">2.342</td> <td align="center">-</td> <td align="center">-</td> </tr> </table> <p>C. Other Program Funding Summary (\$ in Millions)</p> <p>N/A</p> <p>Remarks</p>														FY 2013	FY 2014	FY 2015	Title: MEDEVAC Mission Sensor Forward Looking Infrared Radar (FLIR)	2.342	-	-	Articles:	-	-	-	<p>Description: MEDEVAC Mission Sensor (MMS) FLIR for UH-60 aircraft. One of the requirements for the UH-60A/L MEDEVAC is a sensor system that will assist the pilots in locating patient pick-up points and assist them in maintaining situational awareness in night and adverse weather conditions. The MMS is 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 is currently being used in Operation Enduring Freedom (OEF) for the MEDEVAC mission.</p> <p>FY 2013 Accomplishments:</p> <p>Transitioned from VS7 and completed testing and integration of the Talon FLIR into the aircraft suspension to ensure maximum capability of the sensor, while minimizing impact to aircraft performance.</p>				Accomplishments/Planned Programs Subtotals	2.342	-	-
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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) VS8 / MEDEVAC Mission Equipment Package (MEP) - End Dev
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		

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army													Date: March 2014		
Appropriation/Budget Activity 2040 / 5				R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) VS8 / MEDEVAC Mission Equipment Package (MEP) - End Dev					
Product Development (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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
MEDEVAC Mission Sensor Forward Looking Infrared	TBD	Redstone Arsenal, : AL	0.000	1.721		-		-		-		-	-	1.721	-
Subtotal			0.000	1.721		-		-		-		-	-	1.721	-
Support (\$ in Millions)				FY 2013		FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 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	SS/UCA	Redstone Arsenal : AL	0.000	0.621		-		-		-		-	-	0.621	-
Subtotal			0.000	0.621		-		-		-		-	-	0.621	-
			Prior Years	FY 2013	FY 2014		FY 2015 Base		FY 2015 OCO		FY 2015 Total	Cost To Complete	Total Cost	Target Value of Contract	
Project Cost Totals			0.000	2.342	-		-		-		-	-	2.342	-	
Remarks															

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army																Date: March 2014			
Appropriation/Budget Activity 2040 / 5								R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev								Project (Number/Name) VS8 / MEDEVAC Mission Equipment Package (MEP) - End Dev			

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Exhibit R-4A, RDT&E Schedule Details: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) VS8 / <i>MEDEVAC Mission Equipment Package (MEP) - End Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
MEDEVAC Mission Sensor (MMS) FLIR	2	2013	4	2013