

# UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P)					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev							
COST (\$ in Millions)	Prior Years	FY 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	-	22.514	15.594	23.659	-	23.659	32.295	32.270	28.219	28.373	Continuing	Continuing
808: DoD Drug & Vacc Ad	-	8.956	6.888	8.970	-	8.970	17.138	15.825	14.282	14.585	Continuing	Continuing
811: Mil HIV Vac&Drug Dev	-	2.052	0.550	1.078	-	1.078	0.972	0.846	1.009	1.031	Continuing	Continuing
836: Field Medical Systems Advanced Development	-	11.102	7.595	13.332	-	13.332	14.185	15.599	12.928	12.757	Continuing	Continuing
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.404	0.561	0.279	-	0.279	-	-	-	-	-	1.244

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

## Note

FY15 reduction attributed to realignment to other higher priority Army programs.

## A. Mission Description and Budget Item Justification

This program element (PE) funds development of medical materiel within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet future force requirements identified within concept documents and organizational structures. This Program Element also provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans. The Projects supported by this PE are:

(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.

(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 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.

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<b>Exhibit R-2, RDT&amp;E Budget Item Justification:</b> PB 2015 Army	<b>Date:</b> March 2014
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<b>Appropriation/Budget Activity</b> 2040: <i>Research, Development, Test &amp; Evaluation, Army I BA 4: Advanced Component Development &amp; Prototypes (ACD&amp;P)</i>	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>
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(PROJ VS7) funds program upgrades, retrofits, trains, and sustains the fleet of Medical Evacuation legacy helicopters that continue to play a major role in Iraq and Afghanistan. The approved force design increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies. 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>B. Program Change Summary (\$ in Millions)</b>	<b><u>FY 2013</u></b>	<b><u>FY 2014</u></b>	<b><u>FY 2015 Base</u></b>	<b><u>FY 2015 OCO</u></b>	<b><u>FY 2015 Total</u></b>
Previous President's Budget	24.384	15.603	30.796	-	30.796
Current President's Budget	22.514	15.594	23.659	-	23.659
Total Adjustments	-1.870	-0.009	-7.137	-	-7.137
• Congressional General Reductions	-0.044	-0.009			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	0.700	-			
• SBIR/STTR Transfer	-0.489	-			
• Adjustments to Budget Years	-	-	-7.137	-	-7.137
• Other Adjustments	-2.037	-	-	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 808 / DoD Drug & Vacc Ad			
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
808: DoD Drug & Vacc Ad	-	8.956	6.888	8.970	-	8.970	17.138	15.825	14.282	14.585	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 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)**

	<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<b>Title:</b> DoD Drug and Vaccine Advanced Development	8.956	6.888	8.970
<b>Articles:</b>	-	-	-
<b>Description:</b> Funding is provided for the following effort in the development of candidate medical countermeasures for military relevant infectious disease.			
<b>FY 2013 Accomplishments:</b> New Standard Military Insect Repellant: Testing for this product transitioned to advanced development in FY 2011, and funded with Defense Health Program Budget Activity 7 funding as the potential candidates are all commercially available. Topical Antileishmanial Cream: Reviewed evaluations, and data from the Phase 2 safety/effectiveness clinical trials completed in FY12 for the Topical Antileishmanial Cream; completed preparation for Phase 3 Pivotal clinical trials. Dengue Tetravalent Vaccine: Finalized analysis and evaluation of Phase 2 effectiveness and safety data for the vaccine candidate for Dengue with industry partner Sanofi Pasteur. Continued global phase 3 clinical study in 10 countries with 30,000+ enrollees. Joint Biological Agent identification and Diagnostic System (JBAIDS): Transitioned Joint Biological Agent identification and Diagnostic System (JBAIDS) assay planned to advanced development and begin developmental testing. Leishmania Rapid Diagnostic Device (LRDD):			

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<b>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
Completed final process validation for Leishmania Rapid Diagnostic Device (LRDD). Antimalarial Drug, Artesunate Intravenous: Completed FDA approval and transition to Project 849 (Drugs and Vaccines - 6.5) for Antimalarial Drug, Artesunate Intravenous.					
<b>FY 2014 Plans:</b> Topical Antileishmanial Cream: Complete site development efforts for Phase 3 New World pivotal safety and effectiveness clinical trial on a diverse population. Dengue Tetravalent Vaccine: Continue volunteer follow up and subsequent analysis of data from pivotal Phase 3 (safety and effectiveness in 10 countries, over 30000 volunteers) endemic region studies of Dengue Tetravalent Vaccine with commercial partner Sanofi Pasteur, provide Go/No Go decision for pursuit of compressed vaccination schedule for US traveler/military indication. Joint Biological Agent identification and Diagnostic System (JBAIDS): Completed 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): Transition LRDD to Project 849 (Drugs and Vaccines - 6.5) after completion of the analytical testing and Good Manufacturing Practices manufacturing reviews. Preventive Medicine Products: These 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. Infectious Disease Diagnostic: These 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.					
<b>FY 2015 Plans:</b> Topical Antileishmanial Cream is expected to transition in FY14 to Project 849 (Drugs and Vaccines - 6.5) after completion of the site development efforts for Phase 3 New World clinical trial. Expanded Access Treatment Program will continue until FDA approved product is available. Will continue to compile existing documentation from previous clinical and non-clinical studies in FDA format necessary for supplemental New Drug Application (sNDA) for prophylaxis while Glaxo-Smith Kline decision to file a supplemental New Drug Application (sNDA) for prophylaxis is pending. Dengue Tetravalent Vaccine transitioned in FY14 to Project 849 after completion of volunteer follow up and data analysis on pivotal Phase 3 safety and effectiveness clinical trials. Preventive Medicine Products: These products for the control/mitigation of arthropod (insect) borne diseases field testing and evaluation will transition into Advanced Development for several product candidates to begin process validation: 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. Infectious Disease Diagnostic: Will begin assays process validation of enteric point-of-care disease diagnostic assays. Dengue Vaccine Block II: Will transition from Military Infectious Diseases S&T funding and prepare for Phase 2 safety and efficacy trial (24 to 300 subjects) of vaccine candidate in an adult/military population. Treatment for Resistant Wound Infections: Will transition from Military Infectious Diseases S&T funding					

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army		<b>Date:</b> March 2014	
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</b>		<b>FY 2013</b>	<b>FY 2014</b>
and prepare for Phase 2 safety and efficacy trial (24 to 300 subjects) of drug candidate for the Treatment for Resistant Wound Infections.			
<b>Accomplishments/Planned Programs Subtotals</b>		8.956	6.888
<b>C. Other Program Funding Summary (\$ in Millions)</b>			
N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b>			
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.			
<b>E. Performance Metrics</b>			
N/A			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 4						R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 808 / DoD Drug & Vacc Ad					
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	Not Applicable : Not applicable	13.532	1.919		1.939		0.965		-		0.965	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	PO	General Dynamics Information Technology, Frederick MD : Frederick MD	0.000	-		-		1.365		-		1.365	-	1.365	-
Subtotal			13.532	1.919		1.939		2.330		-		2.330	-	-	-
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	Not applicable : Not applicable	20.778	2.049		2.066		1.374		-		1.374	Continuing	Continuing	Continuing
Product Development of Malaria Prophylaxis	Various	Walter Reed Army Institute of Research : Silver Spring, MD	0.000	3.000		-		-		-		-	-	3.000	-
Product Development of Malaria Prophylaxis	Allot	Armed Forces Research Institute of Medical Sciences : Cambodia	0.000	-		2.111		-		-		-	-	2.111	-
Product Development of Malaria Prophylaxis	Allot	TBD : TBD	0.000	-		-		1.010		-		1.010	-	1.010	-
Subtotal			20.778	5.049		4.177		2.384		-		2.384	-	-	-
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	Not Applicable : Not applicable	7.816	1.388		0.448		1.097		-		1.097	Continuing	Continuing	Continuing

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<b>Exhibit R-3, RDT&amp;E Project Cost Analysis:</b> PB 2015 Army													<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 2040 / 4						<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev				<b>Project (Number/Name)</b> 808 / DoD Drug & Vacc Ad					
<b>Support (\$ in Millions)</b>				<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>			
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
<b>Subtotal</b>			7.816	1.388		0.448		1.097		-		1.097	-	-	-
<b>Test and Evaluation (\$ in Millions)</b>				<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>			
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
Medical Product Development T&E Cost	Various	Not applicable : Not applicable	44.118	0.600		0.324		1.160		-		1.160	Continuing	Continuing	Continuing
Malaria Prophylaxis clinical trial	TBD	TBD : TBD	0.000	-		-		1.999		-		1.999	-	1.999	-
<b>Subtotal</b>			44.118	0.600		0.324		3.159		-		3.159	-	-	-
			<b>Prior Years</b>	<b>FY 2013</b>	<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>	
<b>Project Cost Totals</b>			86.244	8.956		6.888		8.970		-		8.970	-	-	-
<b>Remarks</b>															

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<b>Exhibit R-4, RDT&amp;E Schedule Profile:</b> PB 2015 Army	<b>Date:</b> March 2014
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<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>
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	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
Topical Antileishmanial Cream Phase Expanded Access Treatment Program																												
Malaria Prophylaxis Clinical Trials Safety and Effectiveness Clinical Trials																												
Infectious Disease Diagnostics Assays Validation of point-of-care																												
Dengue Vaccine Block II Phase 2 safety and efficacy trial preparation/perform																												
Arthropod Control / Surveillance Process Validation																												
Treatment for Resistant Wound Infections Phase 2 safety and efficacy trial																												



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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2015 Army			<b>Date:</b> March 2014
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 808 / <i>DoD Drug &amp; Vacc Ad</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Topical Antileishmanial Cream Phase Expanded Access Treatment Program	2	2011	1	2017
Malaria Prophylaxis Clinical Trials Safety and Effectiveness Clinical Trials	3	2010	4	2013
Infectious Disease Diagnostics Assays Validation of point-of-care	1	2015	4	2016
Dengue Vaccine Block II Phase 2 safety and efficacy trial preparation/perform	1	2015	4	2016
Arthropod Control / Surveillance Process Validation	1	2015	4	2017
Treatment for Resistant Wound Infections Phase 2 safety and efficacy trial	1	2015	4	2016

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 811 / 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
811: Mil HIV Vac&Drug Dev	-	2.052	0.550	1.078	-	1.078	0.972	0.846	1.009	1.031	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 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)												
Title: Military HIV Vaccine & Drug Development									FY 2013	FY 2014	FY 2015	
									2.052	0.550	1.078	
Articles:									-	-	-	
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 2013 Accomplishments: Completed three inter-related previous clinical trials aimed at refining our understanding of immune responses elicited by the increment 1 HIV vaccine strategy. Analyzed laboratory interrogation of samples from trial participants.												
FY 2014 Plans: 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. Analyze laboratory interrogation of samples from trial participants. Refine vaccine administration schedule as well as clinical trial design based on data from clinical trials. Safety and effectiveness clinical trial RV305, examine the immune responses to secondary boost of increment 1 HIV regional vaccine. Safety and effectiveness clinical trial RV306, examine the intensive immune monitoring of Prime-Boost Vaccine. Safety and effectiveness clinical trial RV328, conduct intensive immune monitoring of AIDSVAXB/E 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. Adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine effectiveness to initiate in FY14.												
FY 2015 Plans:												

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<b>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</b>		<b>FY 2013</b>	<b>FY 2014</b>
Will begin analysis of samples from safety and effectiveness clinical trial RV305 including extensive evaluation of binding antibodies based on previously determined correlates of protection. In addition, novel findings in cellular immune responses in the stomach have driven new requirements for evaluation of cytotoxic T cell responses in the peripheral blood. During FY15 collection of late invasive samples for safety and effectiveness clinical trials RV306 and RV328 will be completed; those samples have a requirement for immediate processing and analysis. During FY15 RV306 and 328 should conclude, with closing costs associated with the 5 clinical trial sites associated with those protocols. Additional funding for analysis of safety and immunogenicity data by EMMES Corporation will be required. In addition, there will be costs in FY15 from analysis of new lots of the gp120 to be used in efficacy trials currently approved for FY16-17 . We anticipate these costs to be a) analysis of new immunogens in antigenicity assays; b) preclinical animal studies; c) safety and tox; d) bridging study against gp120 AIDSVAX B/E. In addition further support of stability of AIDSVAX will be required.			
<b>Accomplishments/Planned Programs Subtotals</b>		2.052	0.550
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A			
<b>Remarks</b>			
<b>D. Acquisition Strategy</b> Test and evaluate commercially developed drug/vaccine candidates in government-managed trials.			
<b>E. Performance Metrics</b> N/A			

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 4						R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 811 / 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	TBD	Not Applicable : Not Applicable	1.497	0.456		0.165		0.146		-		0.146	Continuing	Continuing	Continuing
Subtotal			1.497	0.456		0.165		0.146		-		0.146	-	-	-
Remarks Not Applicable															
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	TBD	Not applicable : Not applicable	2.618	0.574		0.115		0.550		-		0.550	Continuing	Continuing	Continuing
Subtotal			2.618	0.574		0.115		0.550		-		0.550	-	-	-
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	TBD	TBD : TBD	0.937	0.534		0.101		0.250		-		0.250	-	1.822	-
Subtotal			0.937	0.534		0.101		0.250		-		0.250	-	1.822	-
Remarks Not Applicable															
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	TBD	Not applicable : Not Applicable	15.119	0.488		0.169		0.132		-		0.132	-	15.908	-

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<b>Exhibit R-3, RDT&amp;E Project Cost Analysis:</b> PB 2015 Army												<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 2040 / 4						<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>				<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>				

  

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
<b>Subtotal</b>			15.119	0.488		0.169		0.132		-		0.132	-	15.908	-

  

<b>Remarks</b> Not Applicable															
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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
<b>Project Cost Totals</b>	20.171	2.052	0.550	1.078	-	1.078	-	-	-

  

<b>Remarks</b>									
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<b>Exhibit R-4, RDT&amp;E Schedule Profile: PB 2015 Army</b>	<b>Date:</b> March 2014
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<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>
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	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
RV305 Immune Responses to Secondary Boost of Regional Vaccine																												
RV306 Intensive Immune Monitoring of Prime-Boost Vaccine																												
RV328 Intensive Immune Monitoring of AIDSVAXB/E alone																												
Regional Vaccine Large Well Controlled Large Trial to Test Immunity of Vaccine																												
Prime/Boost Regional Study to Confirm Safety and Effectiveness in a Diverse Pop.																												

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2015 Army			<b>Date:</b> March 2014
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 811 / <i>Mil HIV Vac&amp;Drug Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
RV305 Immune Responses to Secondary Boost of Regional Vaccine	1	2013	2	2014
RV306 Intensive Immune Monitoring of Prime-Boost Vaccine	2	2011	4	2017
RV328 Intensive Immune Monitoring of AIDSVAXB/E alone	1	2012	4	2015
Regional Vaccine Large Well Controlled Large Trial to Test Immunity of Vaccine	3	2014	4	2018
Prime/Boost Regional Study to Confirm Safety and Effectiveness in a Diverse Pop.	1	2016	4	2020

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 836 / Field Medical Systems Advanced 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
836: Field Medical Systems Advanced Development	-	11.102	7.595	13.332	-	13.332	14.185	15.599	12.928	12.757	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
# The FY 2015 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 2013	FY 2014	FY 2015	
Title: Field Medical Systems Advanced Development - PM Medical Devices  Articles:  Description: Advanced Concept Development funding is provided for the following development of medical devices in support of enhanced combat casualty care.  FY 2013 Accomplishments: 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 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-Analyze 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 re-baseline plan in January 2012 for next steps to reach MSB in FY 2013-FY 2014. Fibrinogen Bandages: Phase I clinical trial to began 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									5.944	7.519	11.798	
									-	-	-	



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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2015 Army			<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 2040 / 4		<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>		<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>	
<b>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</b>			<b>FY 2013</b>	<b>FY 2014</b>	<b>FY 2015</b>
<p>III Handheld): enrollment for clinical trials continued and identified a handheld platform for independent testing in June 2012. Milestone B review scheduled.</p> <p><b>FY 2014 Plans:</b>            Eye Tracking System for Assessing Concussions (system is a traumatic brain injury diagnostic tool): Re-baseline, 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 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. Submission of a new 510(k) to cover the expanded indications for the currently fielded device. Device will no longer be a stand-alone product, because the capability will be incorporated in existing ventilators. Plan to transition Hydration Status Monitor (HSM) 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.</p> <p><b>FY 2015 Plans:</b>            Eye Tracking System for Assessing Concussions: Noninvasive neurodiagnostic technologies for TBI is multi-focused. The Eye Tracking System for Assessing Concussions (system is a traumatic brain injury diagnostic tool) is one of multiple systems to be evaluated. Efforts to collate all non-invasive technologies into one integrated IPT is 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. No Research Development Test Evaluation (RDTE) funds are needed for FY15. This project line is being programmed in FY16-20 plan under non-invasive neurodiagnostic line item. TBI Diagnostic Assay System: This effort has seen a dramatic realignment of effort and scope away from Banyan Technologies to Abbott Labs. The focus of this effort will be 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. Once contracting efforts are completed, a path forward will be developed. Impedance Threshold Device for the Treatment of TBI: Current device has a 510(k) (Premarket Notification) clearance for multiple indications. Will continue the submission of a new 510(k) is planned to cover the expanded indications for the currently fielded device. Device will no longer be a stand-alone product, because the capability will be incorporated in existing ventilators. Hydration Status Monitor (HSM) transition was delayed until FY15. Milestone B for this effort is scheduled for Feb 2015. Contract is planned to be a 4 year effort to develop the actual device and gain FDA approval for use. Compartment Syndrome Pressure Device: Will transition from project 840 6.3 funding and enroll patients in the pivotal trial for FDA clearance for anticipated FY15 start of the clinical trial.</p>					
<b>Title:</b> Field Medical Systems Advanced Development - PM Pharmaceuticals  <div style="text-align: right;"><b>Articles:</b></div>			2.486 -	- -	- -

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 836 / Field Medical Systems Advanced Development		
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2013	FY 2014	FY 2015
<p><b>Description:</b> Funding is provided for advanced concept development of biologic medical products managed by PM Pharmaceuticals.</p> <p><b>FY 2013 Accomplishments:</b> Blood Pathogen Reduction/Inactivation transitioned to advanced development in FY 2012, transitioning from Army to be funded with Defense Health Program RDT&amp;E funding. Freeze-dried Plasma: Transitioned to Freeze-dried Plasma program to maintain current schedule and avoid delays. Conducted 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. Freeze-Dried Plasma program: completed Phase 2 clinical trial of safety and effectiveness through a Cooperative Agreement with industry partner. Cryopreserved Platelets: Conducted Milestone B decision reviews for both Cryopreserved Platelets and Freeze-Dried Plasma Programs (new high priority from DoD leadership) and transition to Project 832. Cryopreserved Platelets: start Phase 2 safety/effectiveness clinical trial in cancer patients with platelet deficiency.</p>				
<p><b>Title:</b> Field Medical Systems Advanced Development - PM Medical Support Systems</p> <p><b>Articles:</b></p> <p><b>Description:</b> Funding is provided for the following effort in the development of products that support the medical mission in combat casualty care and health care operations.</p> <p><b>FY 2013 Accomplishments:</b> PM Heavy Brigade Combat Team (HBCT): Prepared and completed testing of the Treatment Table and Blood Refrigerator prototypes for PM Heavy Brigade Combat Team (HBCT). Product transitioned to Project 832 . Transitioned advanced cold chain technologies, trauma tiered medical bag, hoist aeromedical evacuation litter, and quad fold litter to Project 832 and continued development. ISO Panel: Transitioned ISO panel development and Force Provider soft walled module components to Project 832 to finalize development. Environmental Sentinel Biomonitor: Developed prototype for Environmental Sentinel Biomonitor, which transitioned from Science &amp; Technology. Insecticide impregnated bed net: Applied funding from terminated project Shock and Vibration Litter System to this SBIR Phase II product. Acquired data for EPA approval. PEO Combat Support /Combat Service Support: Collaborated with PEO Combat Support/Combat Service Support on development efforts for emerging medical vehicle evacuation variants.</p> <p><b>FY 2014 Plans:</b> Environmental Sentinel Biomonitor: 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. PEO Combat Support /Combat Service Support: Continue collaboration with</p>		2.672 -	0.076 -	1.534 -

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014		
Appropriation/Budget Activity 2040 / 4		R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) 836 / Field Medical Systems Advanced Development	
<b>B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)</b> Program Executive Office Combat Support/Combat Service Support (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). Improved Vector Tent Traps: Develop prototypes of Vector Tent Traps for testing after transition from S&T. The Vector Tent Trap allows researchers to safely conduct vector surveillance on insects that are attracted to humans and vector-borne diseases. Altitude Readiness Management System (ARMS): 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.  <b>FY 2015 Plans:</b> PEO Combat Support /Combat Service Support: Will continue collaboration with Program Executive Office Combat Support/ Combat Service Support (PEO CS&CSS) and Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for emerging medical vehicle evacuation/casualty evacuation (CASEVAC) variants. Improved Vector Tent Traps: Continue prototype development of Vector Tent Traps and transition to project 832. Altitude Readiness Management System (ARMS): Will continue prototype development of the Altitude Readiness Management System (ARMS) and transition to project 832. Next Generation Uniform Repellent: Will begin development of the Next Generation Uniform Repellent (NGUR). The NGUR will transition from an S&T SBIR. The NGUR is an effort to develop new military uniform insect repellent formulations for the uniform materiel and the corresponding uniform treatment technology . Next Generation Immobilization System: Will transition from S&T SBIR. Will develop prototypes for initial developmental testing and FDA data collection. The Next Generation Immobilization System (NGIS) will provide advanced vibration dampening to allow for safer evacuation of spinal cord injury and traumatic brain injury casualties.		FY 2013	FY 2014	FY 2015
Accomplishments/Planned Programs Subtotals		11.102	7.595	13.332
<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A <b>Remarks</b>  <b>D. Acquisition Strategy</b> Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.  <b>E. Performance Metrics</b> N/A				

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 4						R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 836 / Field Medical Systems Advanced 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	Not Applicable : Not applicable	39.609	0.622		0.024		0.933		-		0.933	Continuing	Continuing	Continuing
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	TBD	Banyan BioMarkers, Inc : Alachua FL	0.000	-		0.208		-		-		-	-	0.208	-
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems, Inc : Roseville, MN	0.000	-		0.154		-		-		-	-	0.154	-
Subtotal			39.609	0.622		0.386		0.933		-		0.933	-	-	-
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
Product Development	TBD	TBD : TBD	0.000	-		-		0.932		-		0.932	-	0.932	-
Product Development	TBD	Banyan BioMarkers, Inc : Alachua FL	27.000	4.514		-		-		-		-	Continuing	Continuing	Continuing
Product Development	TBD	HemCon Medical Technologies : Tigard, Oregon	9.720	-		-		-		-		-	Continuing	Continuing	Continuing
Development of Platelet Derived Hemostatic agent	TBD	Fast Track Drugs & Biologics : Frederick, MD	1.800	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development	TBD	ALL Product : Various	1.931	-		-		-		-		-	Continuing	Continuing	Continuing
Product Development of Freeze-dried plasma	TBD	TBD : TBD	0.000	2.400		-		6.884		-		6.884	Continuing	Continuing	Continuing
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	TBD	Banyan BioMarkers, Inc : Alachua FL	0.000	-		5.666		-		-		-	-	5.666	-

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<b>Exhibit R-3, RDT&amp;E Project Cost Analysis: PB 2015 Army</b>													<b>Date:</b> March 2014		
<b>Appropriation/Budget Activity</b> 2040 / 4						<b>R-1 Program Element (Number/Name)</b> PE 0603807A / Medical Systems - Adv Dev				<b>Project (Number/Name)</b> 836 / Field Medical Systems Advanced Development					
<b>Product Development (\$ in Millions)</b>				<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>			
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc. : Roseville, MN	0.000	-		1.250		-		-		-	-	1.250	-
Compartment Syndrome Pressure Device	TBD	Twinstar : Minniapolis, MN	0.000	-		-		1.878		-		1.878	-	1.878	-
Hydration Status Monitor	TBD	Gaia Medical : LaJolla CA	0.000	-		-		0.841		-		0.841	-	0.841	-
<b>Subtotal</b>			40.451	6.914		6.916		10.535		-		10.535	-	-	-
<b>Support (\$ in Millions)</b>				<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>			
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
Medical Product Development Support Cost	Various	Not Applicable : Not applicable	42.799	1.066		0.200		0.932		-		0.932	Continuing	Continuing	Continuing
<b>Subtotal</b>			42.799	1.066		0.200		0.932		-		0.932	-	-	-
<b>Remarks</b> No product/contract costs greater than \$1M individually.															
<b>Test and Evaluation (\$ in Millions)</b>				<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>			
<b>Cost Category Item</b>	<b>Contract Method &amp; Type</b>	<b>Performing Activity &amp; Location</b>	<b>Prior Years</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Award Date</b>	<b>Cost</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
Medical Product Development T&E Cost	TBD	Not applicable : Not applicable	33.468	2.500		0.093		0.932		-		0.932	Continuing	Continuing	Continuing
<b>Subtotal</b>			33.468	2.500		0.093		0.932		-		0.932	-	-	-
<b>Remarks</b> No product/contract costs greater than \$1M individually.															

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army											Date: March 2014			
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) 836 / Field Medical Systems Advanced Development					
		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		156.327	11.102		7.595		13.332		-		13.332	-	-	-

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems - Adv Dev</i>	Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i>	

	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) Critical Design Review MS-B																												
Cryopreserved Platelets (CPP) Phase 1 Safety Clinical Trial																												
Bench-top/POC Biomarker assay for determining exposure to Traumatic Brain Injury																												
Impedance Threshold Device for the Treatment of TBI (PreMarket Note.)																												
Compartment Syndrome Pressure Device MS-A																												
Handheld Biomarker assay for determining exposure to TBI (Increment III)																												
Hydration Status Monitor MS-B																												
Noninvasive Neuromodulator TBI MS-A																												
Environmental Sentinel Biomonitor MS-B																												

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2015 Army			<b>Date:</b> March 2014
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> 836 / <i>Field Medical Systems Advanced Development</i>	

## Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Cryopreserved Platelets (CPP) Critical Design Review MS-B	4	2014	4	2014
Cryopreserved Platelets (CPP) Phase 1 Safety Clinical Trial	4	2011	3	2014
Bench-top/POC Biomarker assay for determining exposure to Traumatic Brain Injury	1	2014	1	2014
Impedance Threshold Device for the Treatment of TBI (PreMarket Note.)	3	2013	2	2014
Compartment Syndrome Pressure Device MS-A	4	2013	4	2013
Handheld Biomarker assay for determining exposure to TBI (Increment III)	4	2013	4	2013
Hydration Status Monitor MS-B	4	2015	4	2015
Noninvasive Neuromodulator TBI MS-A	4	2014	4	2014
Environmental Sentinel Biomonitor MS-B	1	2013	1	2013



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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army										Date: March 2014		
Appropriation/Budget Activity 2040 / 4					R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv 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
VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev	-	0.404	0.561	0.279	-	0.279	-	-	-	-	-	1.244
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
# The FY 2015 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 2013	FY 2014	FY 2015	
Title: Telemedicine for MEDEVAC aircraft  Articles:  Description: Effort is focused on requirement to provide enroute patient data to treatment facilities.  FY 2013 Accomplishments: Designed, developed, and tested 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: 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.									0.404	0.561	-	
									-	-	-	
Title: Medical Evacuation Enroute Care Validation Study  Description: Medical Evacuation Enroute Care Validation Study  FY 2015 Plans: Interim MEDEVAC Mission Support System (IMMSS) will be modified to take into account the new paramedic skills being used by the flight paramedic.									-	-	0.279	
Accomplishments/Planned Programs Subtotals									0.404	0.561	0.279	

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Exhibit R-2A, RDT&E Project Justification: PB 2015 Army		Date: March 2014
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev
C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC and regulatory requirements for production and fielding.		
E. Performance Metrics N/A		

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2015 Army												Date: March 2014			
Appropriation/Budget Activity 2040 / 4						R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev				Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv 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	TBD	APM MEDEVAC : Huntsville, AL	0.152	0.037		-		-		-		-	-	0.189	-
Subtotal			0.152	0.037		-		-		-		-	-	0.189	-
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	TBD	APM MEDEVAC PEO Aviation : Huntsville AL	1.112	0.367		-		-		-		-	-	1.479	-
Subtotal			1.112	0.367		-		-		-		-	-	1.479	-
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	TBD	APM MEDEVAC : Huntsville, AL	0.100	-		0.561		0.279		-		0.279	-	0.940	-
Subtotal			0.100	-		0.561		0.279		-		0.279	-	0.940	-
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	MIPR	APM MEDEVAC PEO Aviation : Huntsville, AL	0.199	-		-		-		-		-	-	0.199	-
Subtotal			0.199	-		-		-		-		-	-	0.199	-

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<b>Exhibit R-3, RDT&amp;E Project Cost Analysis:</b> PB 2015 Army										<b>Date:</b> March 2014			
<b>Appropriation/Budget Activity</b> 2040 / 4					<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>					<b>Project (Number/Name)</b> VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>			
	<b>Prior Years</b>	<b>FY 2013</b>		<b>FY 2014</b>		<b>FY 2015 Base</b>		<b>FY 2015 OCO</b>		<b>FY 2015 Total</b>	<b>Cost To Complete</b>	<b>Total Cost</b>	<b>Target Value of Contract</b>
<b>Project Cost Totals</b>	1.563	0.404		0.561		0.279		-		0.279	-	2.807	-
<b>Remarks</b>													

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Exhibit R-4, RDT&E Schedule Profile: PB 2015 Army			Date: March 2014
Appropriation/Budget Activity 2040 / 4	R-1 Program Element (Number/Name) PE 0603807A / Medical Systems - Adv Dev	Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv 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

Telemedicine Research and Development and Tech transfer																												
Medical Evacuation Enroute Care Validation Study																												

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<b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2015 Army			<b>Date:</b> March 2014
<b>Appropriation/Budget Activity</b> 2040 / 4	<b>R-1 Program Element (Number/Name)</b> PE 0603807A / <i>Medical Systems - Adv Dev</i>	<b>Project (Number/Name)</b> VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Telemedicine Research and Development and Tech transfer	1	2012	4	2015
Medical Evacuation Enroute Care Validation Study	3	2013	4	2014