Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Army											Date: February 2015	
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 2014**	**FY 2015**	**FY 2016 Base**	**FY 2016 OCO**	**FY 2016 Total**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**	**Cost To Complete**	**Total Cost**
Total Program Element	-	33.890	30.384	45.412	-	45.412	42.817	44.150	53.065	57.369	Continuing	Continuing
812: *Mil HIV Vac&Drug Dev*	-	3.770	1.499	5.031	-	5.031	4.812	5.475	5.588	5.751	Continuing	Continuing
832: *Field Medical Systems Engineering Development*	-	18.081	18.197	25.029	-	25.029	24.610	25.212	32.495	35.030	Continuing	Continuing
849: *Infec Dis Drug/Vacc Ed*	-	12.039	10.688	14.953	-	14.953	13.281	13.349	14.982	16.588	Continuing	Continuing
VS8: *MEDEVAC Mission Equipment Package (MEP) - End Dev*	-	-	-	0.399	-	0.399	0.114	0.114	-	-	Continuing	Continuing

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 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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2016 Army	Date: February 2015
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*

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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total
Previous President's Budget	39.447	30.397	48.304	-	48.304
Current President's Budget	33.890	30.384	45.412	-	45.412
Total Adjustments	-5.557	-0.013	-2.892	-	-2.892
• Congressional General Reductions	-	-0.013			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-4.292	-			
• SBIR/STTR Transfer	-1.265	-			
• Adjustments to Budget Years	-	-	-2.892	-	-2.892

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
812: *Mil HIV Vac&Drug Dev*	-	3.770	1.499	5.031	-	5.031	4.812	5.475	5.588	5.751	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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)	FY 2014	FY 2015	FY 2016
Title: Military HIV Vaccine and Drug Development	3.770	1.499	5.031
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 2014 Accomplishments:*** Continued to refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Adjusted 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 Population, planned to begin in early 2018. ***FY 2015 Plans:*** Continue to refine vaccine administration schedule as well as clinical trial design based on data from previous clinical trials. Continue to adjust plan for Regional well-controlled clinical trial large enough to demonstrate vaccine efficacy which initiated mid-2013. ***FY 2016 Plans:*** Will begin early testing of new Envelope glycoprotein 120 bivalent products in prime-boost formal will allow for efficacy site preparation and potential trial start in Q1 of FY17. Will begin final site selection and ramp up of efficacy trial activities.			
Accomplishments/Planned Programs Subtotals	3.770	1.499	5.031

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

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

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	1.638	0.823		0.173		1.018		-		1.018	Continuing	Continuing	-
		Subtotal	1.638	0.823		0.173		1.018		-		1.018	-	-	-

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Henry M. Jackson Foundation, : Various	32.326	0.951		0.325		2.000		-		2.000	Continuing	Continuing	Continuing
		Subtotal	32.326	0.951		0.325		2.000		-		2.000	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	0.657	0.748		0.301		0.963		-		0.963	Continuing	Continuing	-
		Subtotal	0.657	0.748		0.301		0.963		-		0.963	-	-	-

Test and Evaluation ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Henry M. Jackson Foundation, : Various	25.147	1.248		0.700		1.050		-		1.050	Continuing	Continuing	Continuing
		Subtotal	25.147	1.248		0.700		1.050		-		1.050	-	-	-

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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*	

	Prior Years	FY 2014		FY 2015		FY 2016 Base		FY 2016 OCO		FY 2016 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	59.768	3.770		1.499		5.031		-		5.031	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2016 Army		Date: February 2015
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*

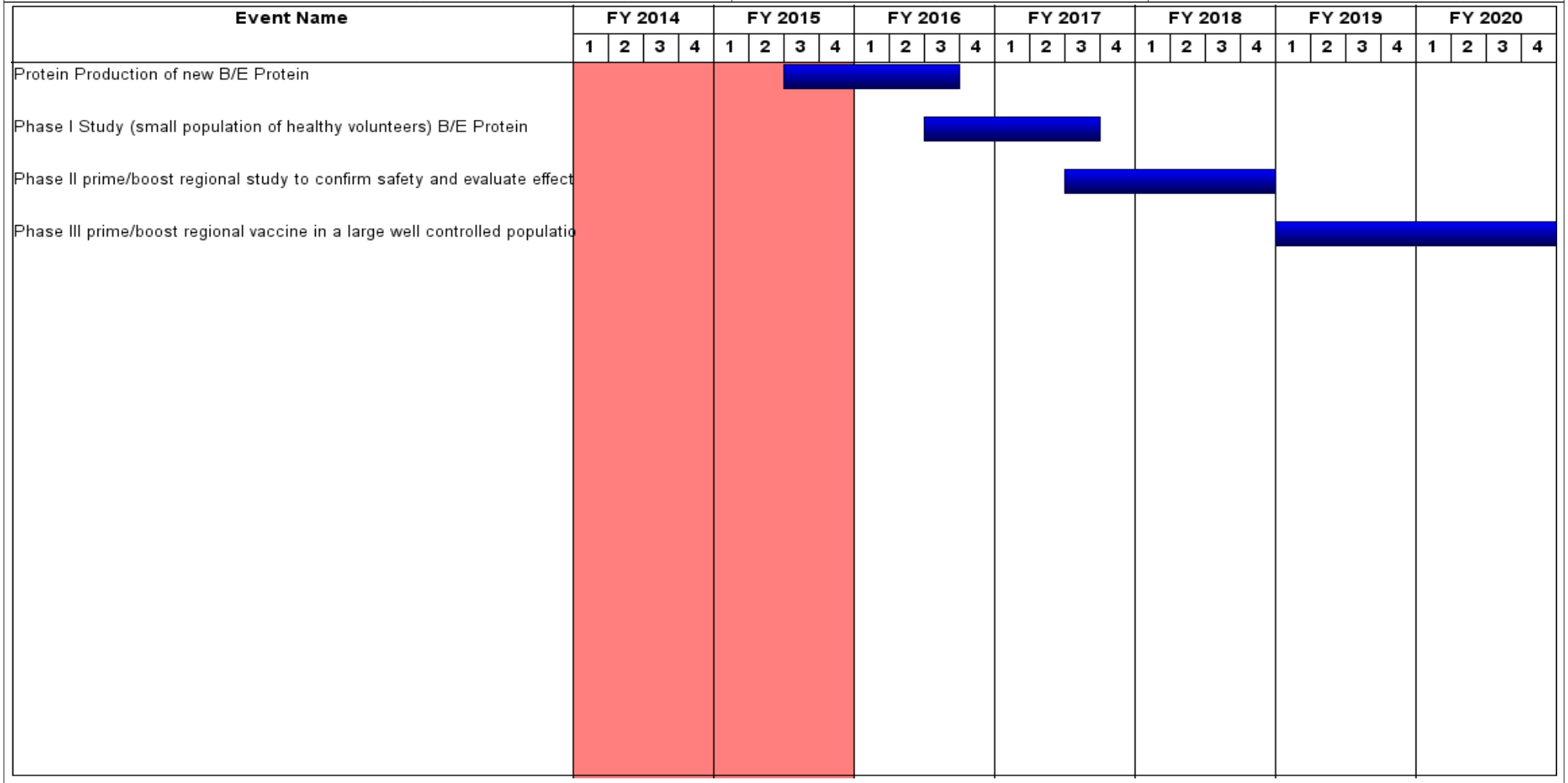

Exhibit R-4A, RDT&E Schedule Details: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 812 / *Mil HIV Vac&Drug Dev*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
Protein Production of new B/E Protein	3	2015	3	2016
Phase I Study (small population of healthy volunteers) B/E Protein	3	2016	3	2017
Phase II prime/boost regional study to confirm safety and evaluate effectiveness	3	2017	4	2018
Phase III prime/boost regional vaccine in a large well controlled population to	1	2019	4	2021

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
832: *Field Medical Systems Engineering Development*	-	18.081	18.197	25.029	-	25.029	24.610	25.212	32.495	35.030	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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)	FY 2014	FY 2015	FY 2016
Title: Field Medical Systems Engineering Development PM Medical Devices	0.943	2.984	3.260
Description: This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by PM Medical Devices.			
FY 2014 Accomplishments: Oxygen Generator (15 LPM) System: 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: Continued planned testing of devices designed and developed in previous years. Medical Equipment Sets Development: Continued development and testing to ensure the most current and cost effective devices are being utilized. Equipment was 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 were available and new technology was 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 prepared to obtain FDA approval once transition from project 836 was completed.			
FY 2015 Plans:			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
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 had 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. Moved this project through the DOD Acquisition process to accommodate the modernization effort. Medical Equipment Sets Development: 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 when products are discontinued, new models are available and new technology introduced to meet the current standard of patient care. TBI Diagnostic Assay System Increment II Point of Care Device: 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 are in place 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 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: Conducting comparative studies for the Advanced Wound Care COTS products (in-vivo animal or human studies).			
FY 2016 Plans: Oxygen Generator (15 LPM) System: In FY16 it is anticipated product will transition out of Adv. Development and be procured with Army procurement (OPA) funds. Replacement for the M-138 Steam Sterilizer: FDA clearance now expected by the end of Fy14 and MS-C scheduled for October 2014 to transition product to procurement. Medical Equipment Sets Development: 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 product has transitioned from Army to DoD RDTE and will be developed with DoD funding. Noninvasive Neurodiagnostics TBI: The 3 technologies currently involved are the Eye-Tracking System, the QEEG and Balance Platforms. None of these system are anticipated to be ready at this time for transition			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
to advanced development. Advanced Wound Dressing: Will continue conducting comparative studies for the Advanced Wound Care commercial products (in-vivo animal or human studies).			
Title: Field Medical Systems Engineering Development PM Pharmaceuticals ***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. ***FY 2014 Accomplishments:*** Cryopreserved Platelets: Completed Phase 2 safety and effectiveness clinical trial in cancer patients with platelet deficiency and continued 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: Continued 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. ***FY 2015 Plans:*** Cryopreserved Platelets: Cryopreserved Platelets schedule will be extended one year due to the FDA requiring an additional safety clinical study. 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. Freeze-Dried Plasma Program: 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 and continue Phase 2b safety clinical study. ***FY 2016 Plans:*** Cryopreserved Platelets: Will continue the Phase 2 Efficacy study in patients with complex cardiac bypass and/or thrombocytopenic patients with World Health Organization Grade 2 or higher bleeding. Will continue development of Phase 3 clinical testing and protocols for pivotal study. Freeze-Dried Plasma Program: Will continue the Phase 2 clinical trials. Will continue manufacturing development and validation of Freeze-Dried Plasma batches.	11.920	10.463	14.978
Title: Field Medical Systems Engineering Development PM Integrated Clinical Systems (ICS) ***Description:*** This project funds the engineering and manufacturing development of medical products managed by PM ICS for enhanced combat casualty care and follow-on care, including rehabilitation. ***FY 2015 Plans:*** Pre-Hospital Medical Informatics Transport: Combat Developers validate requirements for the Pre-Hospital Medical Informatics Transport system. ***FY 2016 Plans:***	-	1.357	4.923

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Pre-Hospital Medical Informatics Transport: Combat Developers will begin the engineering and manufacturing development phase for the Pre-Hospital Medical Informatics Transport:.			
Title: Field Medical Systems Engineering Development PM Medical Support Systems	5.218	3.393	1.868
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 2014 Accomplishments:*** Modernization of medical equipment sets: As part of the medical equipment sets, continued to perform form, fit and function of field medical sink, and continued to evaluate commercial litters and cold chain storage devices. Airworthiness Testing: Continued 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. Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package: Completed operational testing of the ISO operating room shelter and finalized Force Provider soft-walled shelter for procurement. Continued 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 consisted of medical shelters, Mine Resistant Ambush Protected (MRAP), Armored Multipurpose Vehicle (AMPV), and Joint Light Tactical Vehicle (JLTV). Collaborated with PEO GCS on medical variants for the Heavy Brigade Combat Team (HBCT). Environmental Sentinel Biomonitor (ESB): Completed operational testing of the Environmental Sentinel Biomonitor (ESB) when it transitioned from project 836 and conducted 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:*** Modernization of medical equipment sets: As part of the medical equipment sets, complete form, fit and function of field medical sink, continue to evaluate commercial litters, cold chain storage devices and commercial items. Airworthiness Testing: 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. Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package: 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) package. Environmental Sentinel Biomonitor (ESB): Complete operational testing of the Environmental Sentinel Biomonitor (ESB) and conduct a Milestone C (Engineering, Manufacturing and Development phase review). Milestone C start delayed in FY14. The ESB will assist preventative medicine personnel certify water capabilities by providing a presumptive screening			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
capability that can rapidly identify toxicity in water. Waste Treatment System for the CSH: 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): 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. Transition from 836. Improved Vector Trap: 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. Transition from 836. Portable Vector Identification Workstation: Begin development of field deployable Vector Identification Workstation to provide situational awareness necessary to prevent/mitigate vector borne threats and associated environmental hazards. ***FY 2016 Plans:*** Modernization of medical equipment sets: As part of the medical equipment sets, will complete evaluations of 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. Per Army Regulation 70-62, Airworthiness Qualification of Aircraft Systems, all "carry-on" equipment, to include medical devices, must have an Airworthiness release. Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package: Will continue collaboration with Program Executive Office (PEO) Combat Support/Combat Service Support (PEO CS&CSS) and PEO Ground Combat Systems (PEO GCS) on development efforts for AMPV evacuation and treatment platforms. Environmental Sentinel Biomonitor (ESB): Will finish Advanced Development of Environmental Sentinel Biomonitor with a MS C planned for early FY16 and will transition product to procurement. Waste Treatment System for the CSH: Will transition from Small Business Innovation Research in FY16 due to delays in development/ prototype evaluation. Will start development of Waste Treatment System (WTS) for the Combat Support Hospital. Altitude Readiness Management System (ARMS): Will transition the ARMS product to PEO Soldier and closeout the Advance Development effort. Improved Vector Trap: Will continue prototype development of Vector Traps for user evaluation. Portable Vector Identification Workstation: Will complete user evaluation of the field deployable vector identification workstation and add to Entomology Set.			
Accomplishments/Planned Programs Subtotals	18.081	18.197	25.029

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

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

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	25.055	2.664		2.610		1.867		-		1.867	Continuing	Continuing	Continuing
		Subtotal	25.055	2.664		2.610		1.867		-		1.867	-	-	-

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Freeze-dried Human Plasma	Various	HemCon Medical Technologies, Inc, : Tigard OR	27.274	5.476		-		0.033		-		0.033	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	3.510	0.608		1.124		1.548		-		1.548	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		0.359		-		0.359	-	3.470	-
Cryopreserved Platelets	Various	Multiple DoD activities and Dartmouth Hitchcock Med Ctr : North Potomac, MD	14.362	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	0.000	1.450		-		0.500		-		0.500	-	1.950	-
Intracellular Hemorrhage Treatment	TBD	TBD : TBD	0.000	-		-		0.750		-		0.750	-	0.750	-

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	Various	Banyan BioMarkers, Inc : Alachua, FL	0.000	0.373		-		-		-		-	-	0.373	-
Noninvasive Neurodiagnostics	TBD	TBD : TBD	0.000	-		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		4.747		-		4.747	-	5.082	-
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine)	TBD	TBD : TBD	0.000	-		0.950		1.586		-		1.586	-	2.536	-
		Subtotal	63.386	9.107		6.967		9.523		-		9.523	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Regulatory Support	Various	Clinical Research Management,Inc,. : Various	5.557	-		0.659		0.307		-		0.307	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various : Various	5.854	2.807		-		1.548		-		1.548	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various : Various	0.000	0.455		2.342		-		-		-	-	2.797	-
		Subtotal	11.411	3.262		3.001		1.855		-		1.855	-	-	-

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	12.624	1.784		-		1.615		-		1.615	Continuing	Continuing	Continuing
Cryopreserved Platelets	TBD	TBD : TBD	0.000	1.150		1.743		6.101		-		6.101	-	8.994	-
Medical Equipment Sets Development	Various	Various : Various	0.000	0.114		1.092		-		-		-	-	1.206	-
Freeze Dried Plasma	C/CPFF	TBD : TBD	0.000	-		2.784		4.068		-		4.068	-	6.852	-
		Subtotal	12.624	3.048		5.619		11.784		-		11.784	-	-	-

	Prior Years	FY 2014		FY 2015		FY 2016 Base		FY 2016 OCO		FY 2016 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	112.476	18.081		18.197		25.029		-		25.029	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2016 Army		Date: February 2015
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*

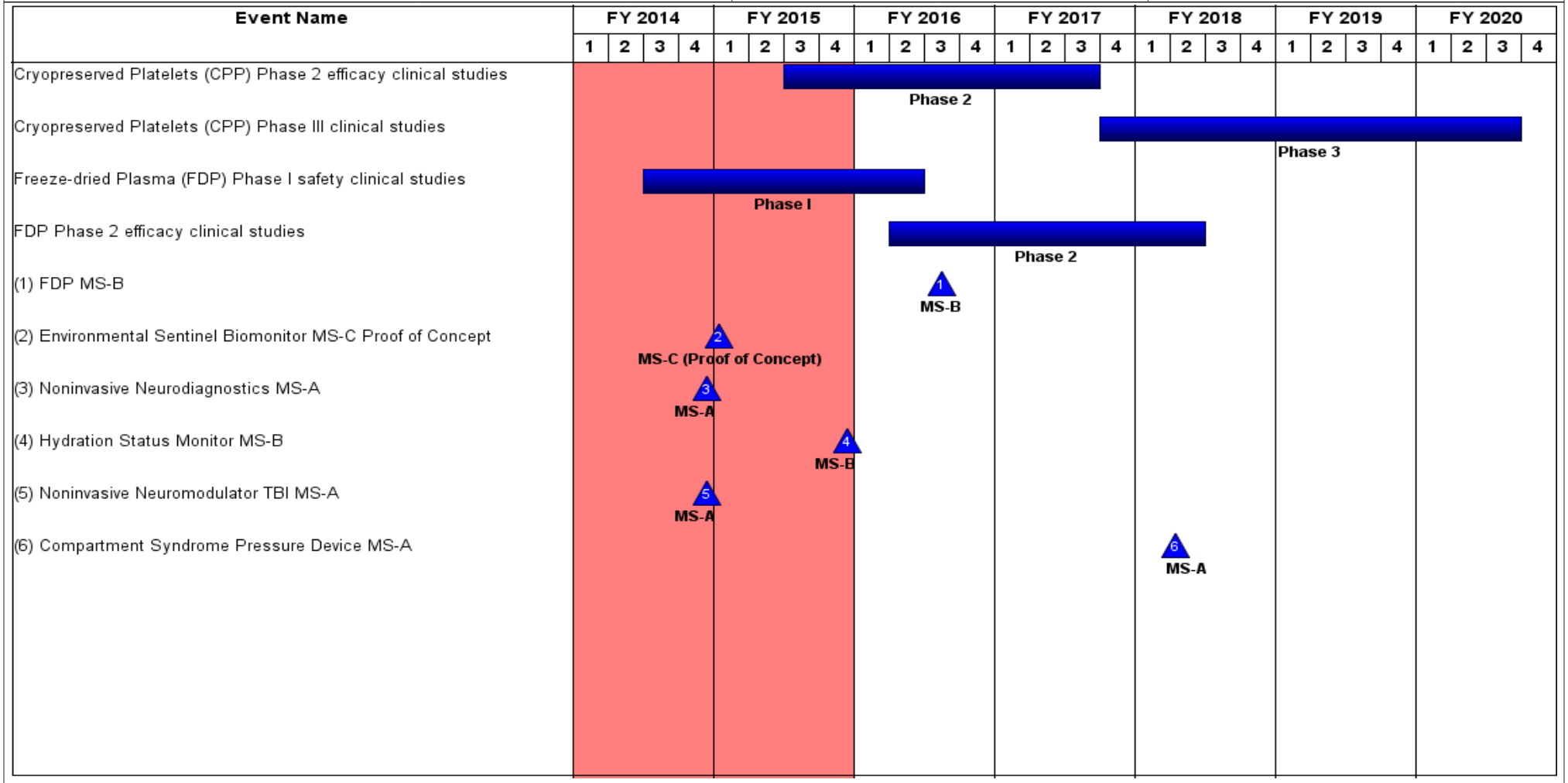

Exhibit R-4A, RDT&E Schedule Details: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 832 / *Field Medical Systems Engineering Development*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies	3	2015	3	2017
Cryopreserved Platelets (CPP) Phase III clinical studies	4	2017	3	2020
Freeze-dried Plasma (FDP) Phase I 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
Hydration Status Monitor MS-B	4	2015	4	2015
Noninvasive Neuromodulator TBI MS-A	4	2014	4	2014
Compartment Syndrome Pressure Device MS-A	2	2018	2	2018

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
849: *Infec Dis Drug/Vacc Ed*	-	12.039	10.688	14.953	-	14.953	13.281	13.349	14.982	16.588	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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)	FY 2014	FY 2015	FY 2016
Title: Infectious Disease Drug and Vaccine Engineering Development	12.039	10.688	14.953
Description: Funding for research and development efforts for Drugs and Vaccines. ***FY 2014 Accomplishments:*** Dengue Tetravalent Vaccine (DTV): Continued 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, continued performance of military-specific needs US adult clinical studies, and continued studies to determine if the vaccine will protect against the disease. Next Generation Malaria Prophylaxis: Continued Pivotal clinical trials and began efforts to determine if licensing in Australia is feasible. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Completed New World Phase 3 (safety and effectiveness clinical trials > 300 subjects) clinical trial and Treatment Protocol for Phase 3 site(s), and completed 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): Conducted milestone C (Engineering, Manufacturing and Development phase			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
review) review, obtained FDA approval, and began fielding. The Leishmania Skin Test (LST) project: The response from the FDA indicated they would only support limited clinical utility and required 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: Planned 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, began field testing and evaluation. Preventive Medicine advanced pesticides: Began field testing and evaluation. Preventive Medicine spatial repellents: Began field testing and evaluation. Preventive Medicine arthropod collection devices: Began field testing and evaluation. Preventive Medicine arthropod collection devices: Began field testing and evaluation. Infectious Disease Diagnostic products: Began field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever.			
FY 2015 Plans: Dengue Tetravalent Vaccine (DTV): Continue patient follow up and complete Phase 3 pivotal clinical trials and adult/military-specific indication studies. 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, continue trial-related activities and data analysis. Validate Commercial Partner production of batches at their dedicated manufacturing facility. Next Generation Malaria Prophylaxis: 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 studies that is no longer needed. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Transition from project 808 in FY14. Complete Phase 3 New World clinical trial in FY15 based on additional guidance and requirements from the FDA. Conduct MS-C decision review and submit New Drug Application to the FDA. Leishmania Rapid Diagnostic Device (LRDD): Complete fielding/delivery of Leishmania Rapid Diagnostic Device. Antimalarial Drug, Artesunate Intravenous: Conduct MS-C decision review and submit New Drug Application to the FDA sent in FY14. Plan to obtain FDA approval in FY15 and begin fielding/delivery of Antimalarial Drug, Artesunate Intravenous. Preventive Medicine advanced detection devices: For the control/mitigation of arthropod (insect) borne diseases, begin field testing and evaluation. Preventive Medicine advanced pesticides: Begin field testing and evaluation. Preventive Medicine spatial repellents: Begin field testing and evaluation. Preventive Medicine arthropod collection devices: 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.			
FY 2016 Plans: Dengue Tetravalent Vaccine (DTV): Will complete Phase 3 pivotal clinical trials and adult/military-specific indication studies. Will submit the master file (product documentation) for endemic countries to the FDA. Will complete Milestone C package. Development of Biologic License Application (BLA) for US Licensure, development of Final reports will near completion for BLA submission in FY17 to the FDA. Commercial Partner will produce validation lots at their dedicated manufacturing facility.			

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Next Generation Malaria Prophylaxis: Will continue to complete New Drug Application preparatory work for filing with the FDA. The IPT will initiate a retinal safety study in 2016 and prepare the protocols for required soldier specific studies that need to be completed. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): The New Drug Application submission package will be completed and submitted to the FDA for approval. The manufacturing process will be validated in preparation for commercial production of the cream. The expanded access and treatment protocols will continue through FY 16. Antimalarial Drug, Artesunate Intravenous: Will continue to support FDA inquiries during the review process of the New Drug Application. Will be working with the commercial partner to support marketing and distribution plans for the drug. Preventive Medicine advanced detection devices: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). As such, they have moved to a more appropriate Program Element (PE 836 or 832) and will be listed as separate products when they are considered for military use. Preventive Medicine advanced pesticides: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). As such, they have moved to a more appropriate Program Element (PE 836 or 832) and will be listed as separate products when they are considered for military use. Preventive Medicine spatial repellents: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). As such, they have moved to a more appropriate Program Element (PE 836 or 832) and will be listed as separate products when they are considered for military use. Preventive Medicine arthropod collection devices: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). As such, they have moved to a more appropriate Program Element (PE 836 or 832) and will be listed as separate products when they are considered for military use. Preventive Medicine arthropod collection devices: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). As such, they have moved to a more appropriate Program Element (PE 836 or 832) and will be listed as separate products when they are considered for military use. Infectious Disease Diagnostic products: Delays in the previous year's transition for infectious disease diagnostic products from S&T are due to product maturity. Will begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever. Dengue Vaccine Block II: Will begin preparation for human challenge efforts to show vaccine efficacy and animal studies to determine correlates of immunity in preparation for Phase III clinical trials. Arthropod Control/Surveillance: Will begin field testing and evaluation of a Dengue Rapid Diagnostic.			
Accomplishments/Planned Programs Subtotals	12.039	10.688	14.953

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

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.

E. Performance Metrics

N/A

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	16.661	2.220		0.265		0.712		-		0.712	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	0.000	-		1.012		2.263		-		2.263	-	3.275	-
		Subtotal	16.661	2.220		1.277		2.975		-		2.975	-	-	-

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various : Various	28.215	4.629		1.326		2.007		-		2.007	Continuing	Continuing	Continuing
Topical Antileishmanial Drug	TBD	TBD : TBD	2.400	-		-		-		-		-	-	2.400	-
Topical Antileishmanial Drug	C/CPFF	Advantar Laboratories, INC : TBD	0.000	-		1.355		0.662		-		0.662	-	2.017	-
Dengue Tetravalent Vaccine	TBD	TBD : TBD	0.000	-		1.525		0.648		-		0.648	-	2.173	-
Hemorrhagic Fever W/ Renal Syndrome	C/TBD	TBD : TBD	0.000	-		-		1.000		-		1.000	-	1.000	-
		Subtotal	30.615	4.629		4.206		4.317		-		4.317	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	14.563	2.624		0.690		1.503		-		1.503	Continuing	Continuing	Continuing

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total 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		0.287		-		0.287	-	3.455	-
		Subtotal	14.563	2.624		3.858		1.790		-		1.790	-	-	-

Test and Evaluation ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	36.467	1.182		1.347		2.725		-		2.725	Continuing	Continuing	Continuing
Product Development of Dengue Tetravalent Vaccine	Various	TBD : TBD	0.000	1.384		-		3.146		-		3.146	-	4.530	-
		Subtotal	36.467	2.566		1.347		5.871		-		5.871	-	-	-

	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	98.306	12.039		10.688		14.953		-		14.953	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2016 Army		Date: February 2015
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*

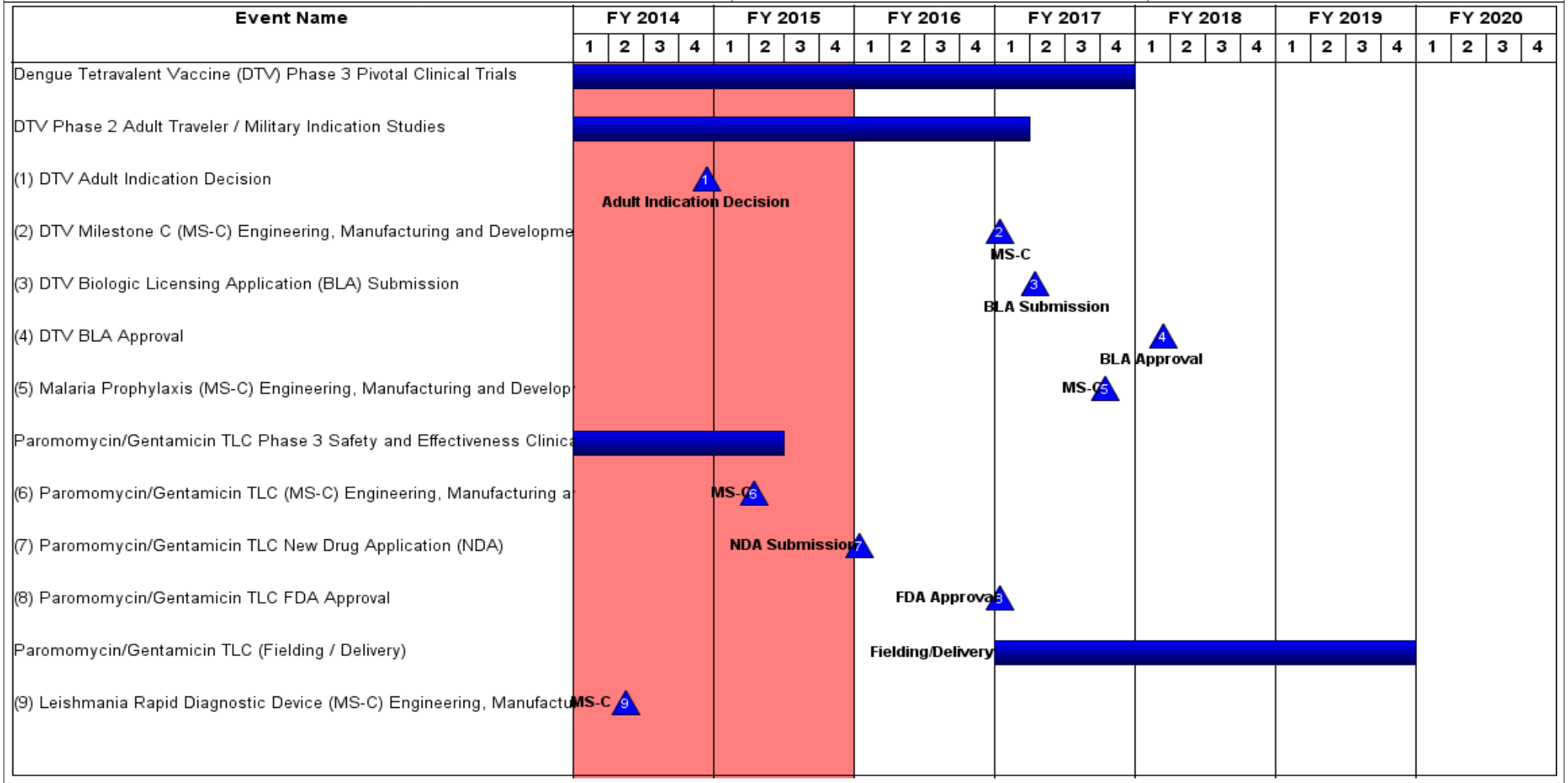

Exhibit R-4, RDT&E Schedule Profile: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 849 / *Infec Dis Drug/Vacc Ed*

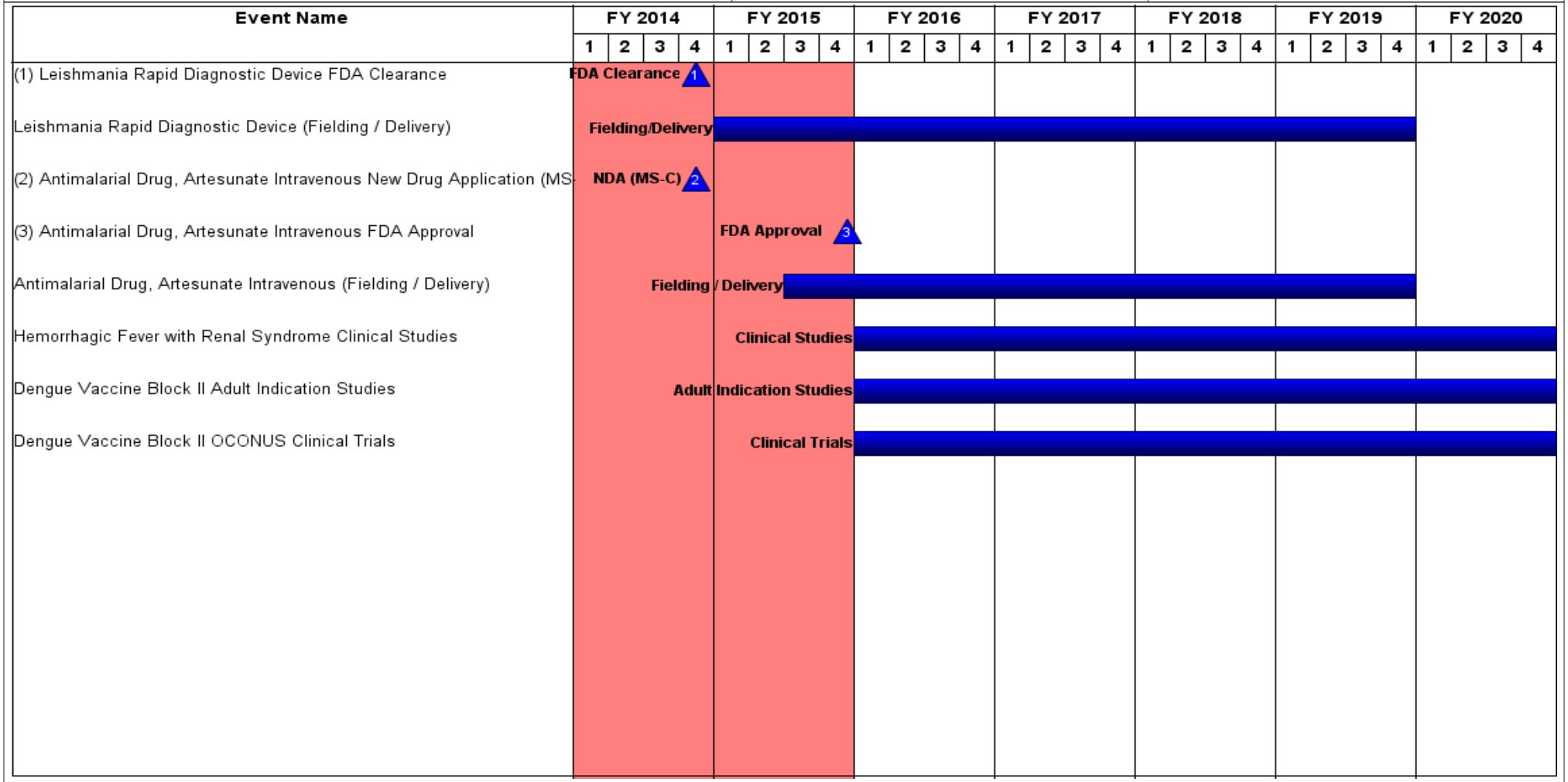

Exhibit R-4A, RDT&E Schedule Details: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 849 / *Infec Dis Drug/Vacc Ed*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials	1	2011	4	2017
DTV Phase 2 Adult Traveler / Military Indication Studies	2	2012	1	2017
DTV Adult Indication Decision	4	2014	4	2014
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review	1	2017	1	2017
DTV Biologic Licensing Application (BLA) Submission	2	2017	2	2017
DTV BLA Approval	1	2018	2	2018
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	2	2015
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development	2	2015	2	2015
Paromomycin/Gentamicin TLC New Drug Application (NDA)	1	2016	1	2016
Paromomycin/Gentamicin TLC FDA Approval	1	2017	1	2017
Paromomycin/Gentamicin TLC (Fielding / Delivery)	1	2017	4	2019
Leishmania Rapid Diagnostic Device (MS-C) Engineering, Manufacturing and Develop	2	2014	2	2014
Leishmania Rapid Diagnostic Device FDA Clearance	4	2014	4	2014
Leishmania Rapid Diagnostic Device (Fielding / Delivery)	1	2015	4	2019
Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)	4	2014	4	2014
Antimalarial Drug, Artesunate Intravenous FDA Approval	4	2015	4	2015
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)	3	2015	4	2019
Hemorrhagic Fever with Renal Syndrome Clinical Studies	1	2016	4	2020
Dengue Vaccine Block II Adult Indication Studies	1	2016	4	2020
Dengue Vaccine Block II OCONUS Clinical Trials	1	2016	4	2020

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army			Date: February 2015
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 2014	FY 2015	FY 2016 Base	FY 2016 OCO	FY 2016 Total	FY 2017	FY 2018	FY 2019	FY 2020	Cost To Complete	Total Cost
VS8: *MEDEVAC Mission Equipment Package (MEP) - End Dev*	-	-	-	0.399	-	0.399	0.114	0.114	-	-	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

Note

Interim MEDEVAC Mission Support System (IMMSS) is not a new start. Funding for this project started in FY 2013.

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 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.

B. Accomplishments/Planned Programs ($ in Millions)	FY 2014	FY 2015	FY 2016
Title: Interim MEDEVAC Mission Support System (IMMSS)	-	-	0.399
Description: Interim MEDEVAC Mission Support System (IMMSS) - Patient Handling System for safely handling patient through a system of seats, patient litters etc. ***FY 2016 Plans:*** Any modifications to the IMMSS that are made based on new paramedic skills will require validation and verification. Will develop plans for required validation and verification to address the new paramedic skills.			
Accomplishments/Planned Programs Subtotals	-	-	0.399

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.

Exhibit R-2A, RDT&E Project Justification: PB 2016 Army		Date: February 2015
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*

E. Performance Metrics

N/A

Exhibit R-3, RDT&E Project Cost Analysis: PB 2016 Army			Date: February 2015
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)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
MEDEVAC Mission Sensor Forward Looking Infrared	TBD	Redstone Arsenal, : AL	1.721	-		-		0.399		-		0.399	-	2.120	-
		Subtotal	1.721	-		-		0.399		-		0.399	-	2.120	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	SS/UCA	Redstone Arsenal : AL	0.621	-		-		-		-		-	-	0.621	-
		Subtotal	0.621	-		-		-		-		-	-	0.621	-

	Prior Years	FY 2014 Cost	FY 2014 Award Date	FY 2015 Cost	FY 2015 Award Date	FY 2016 Base Cost	FY 2016 Base Award Date	FY 2016 OCO Cost	FY 2016 OCO Award Date	FY 2016 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	2.342	-		-		0.399		-		0.399	-	2.741	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2016 Army		Date: February 2015
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*

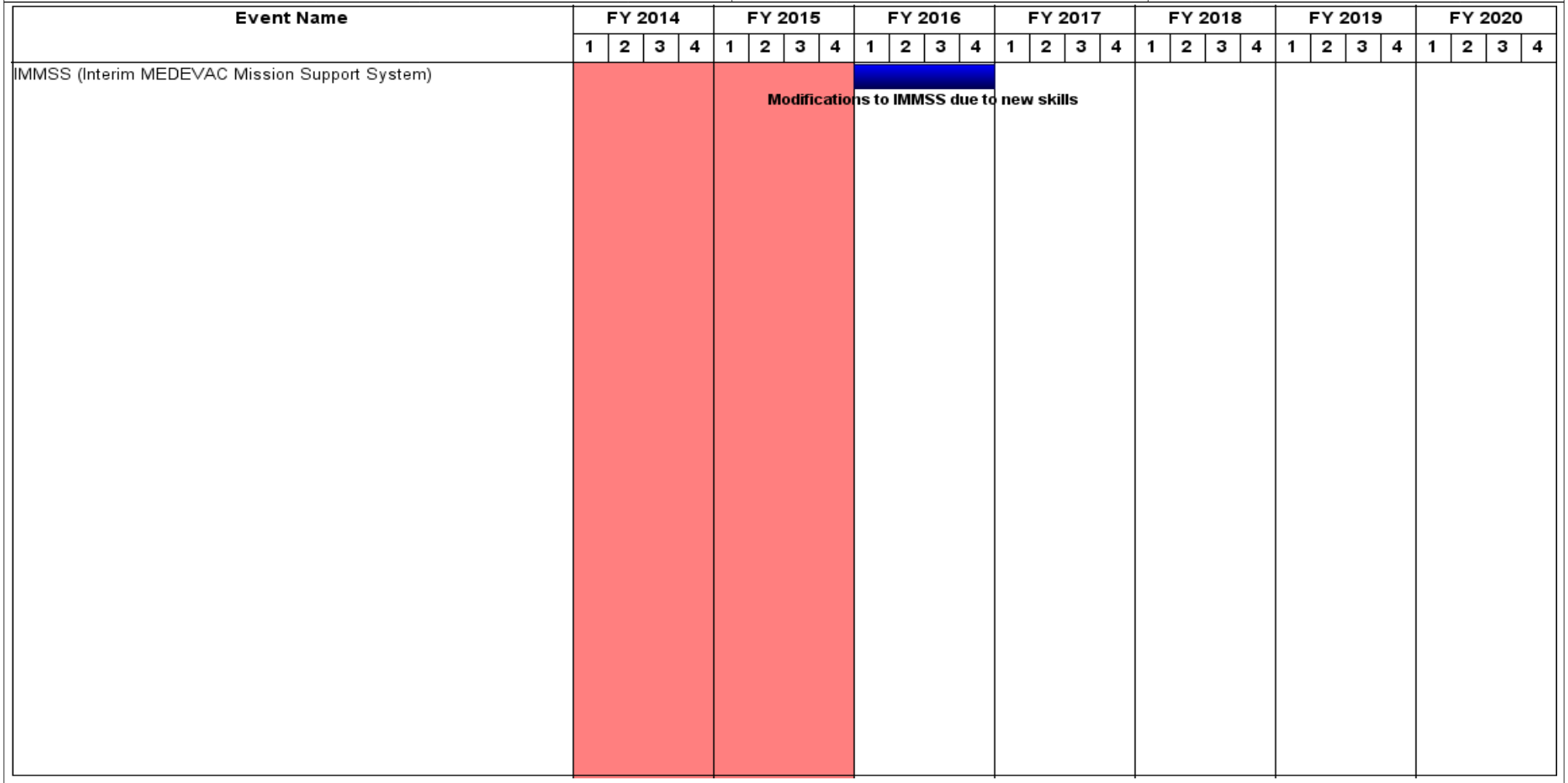

Exhibit R-4A, RDT&E Schedule Details: PB 2016 Army		Date: February 2015
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** VS8 / *MEDEVAC Mission Equipment Package (MEP) - End Dev*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
IMMSS (Interim MEDEVAC Mission Support System)	1	2016	4	2016