Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Army											Date: February 2016	
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 2015**	**FY 2016**	**FY 2017 Base**	**FY 2017 OCO**	**FY 2017 Total**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**Cost To Complete**	**Total Cost**
Total Program Element	-	29.441	45.412	41.124	-	41.124	43.603	52.562	56.893	58.410	Continuing	Continuing
812: *Mil HIV Vac&Drug Dev*	-	1.442	5.031	4.557	-	4.557	5.283	5.408	5.579	5.729	Continuing	Continuing
832: *Field Medical Systems Engineering Development*	-	17.689	25.029	23.532	-	23.532	25.035	32.333	34.877	35.806	Continuing	Continuing
849: *Infec Dis Drug/Vacc Ed*	-	10.310	14.953	12.922	-	12.922	13.171	14.821	16.437	16.875	Continuing	Continuing
VS8: *MEDEVAC Mission Equipment Package (MEP) - End Dev*	-	0.000	0.399	0.113	-	0.113	0.114	0.000	0.000	0.000	Continuing	Continuing

Note

No PE or project change in FY17.

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 (FDA).

(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 in 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.

Exhibit R-2, RDT&E Budget Item Justification: PB 2017 Army	Date: February 2016
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*

(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 Army's force design increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs.

These projects are 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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total
Previous President's Budget	30.384	45.412	42.817	-	42.817
Current President's Budget	29.441	45.412	41.124	-	41.124
Total Adjustments	-0.943	0.000	-1.693	-	-1.693
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.943	-			
• Adjustments to Budget Years	-	-	-1.693	-	-1.693

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
812: *Mil HIV Vac&Drug Dev*	-	1.442	5.031	4.557	-	4.557	5.283	5.408	5.579	5.729	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 2015	FY 2016	FY 2017
Title: Military HIV Vaccine and Drug Development	1.442	5.031	4.557
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 2015 Accomplishments:*** 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:*** 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. Begin final site selection and ramp up of efficacy trial activities. ***FY 2017 Plans:*** Will conduct a Phase IIB efficacy study (trial to evaluate efficacy in patients with the disease) for the global HIV vaccine candidate.			
Accomplishments/Planned Programs Subtotals	1.442	5.031	4.557

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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)

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 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	2.461	0.173		1.018		0.764		-		0.764	Continuing	Continuing	0
		Subtotal	2.461	0.173		1.018		0.764		-		0.764	-	-	0.000

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Henry M. Jackson Foundation, : Various	33.277	0.268		2.000		0.881		-		0.881	Continuing	Continuing	Continuing
		Subtotal	33.277	0.268		2.000		0.881		-		0.881	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	1.405	0.301		0.963		0.944		-		0.944	Continuing	Continuing	0
		Subtotal	1.405	0.301		0.963		0.944		-		0.944	-	-	0.000

Test and Evaluation ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Henry M. Jackson Foundation, : Various	26.395	0.700		1.050		1.968		-		1.968	Continuing	Continuing	Continuing
		Subtotal	26.395	0.700		1.050		1.968		-		1.968	-	-	-

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015		FY 2016		FY 2017 Base		FY 2017 OCO		FY 2017 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	63.538	1.442		5.031		4.557		-		4.557	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2017 Army		Date: February 2016
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*

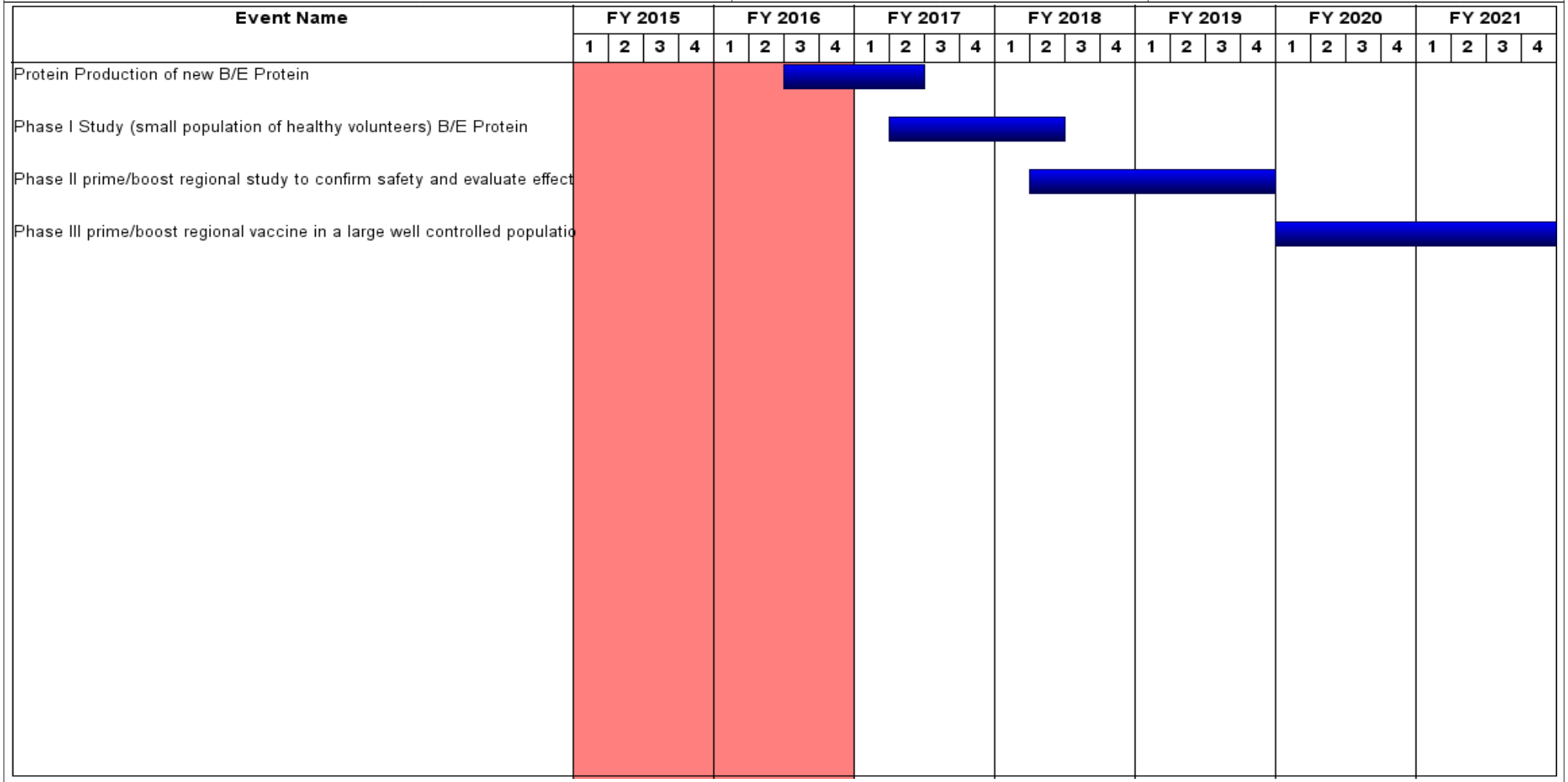

Exhibit R-4A, RDT&E Schedule Details: PB 2017 Army		Date: February 2016
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 812 / *Mil HIV Vac&Drug Dev*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
Protein Production of new B/E Protein	3	2016	2	2017
Phase I Study (small population of healthy volunteers) B/E Protein	2	2017	2	2018
Phase II prime/boost regional study to confirm safety and evaluate effectiveness	2	2018	4	2019
Phase III prime/boost regional vaccine in a large well controlled population	1	2020	4	2021

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
832: *Field Medical Systems Engineering Development*	-	17.689	25.029	23.532	-	23.532	25.035	32.333	34.877	35.806	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 2015	FY 2016	FY 2017
Title: Field Medical Systems Engineering Development PM Medical Devices	2.815	3.260	3.126
Description: This project funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by PM Medical Devices.			
FY 2015 Accomplishments: 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			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
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 transition out of Adv. Development and is to be procured with Army procurement (OPA) funds. Replacement for the M-138 Steam Sterilizer: FDA clearance and MS-C achieved. FRP projected early FY16. 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 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 is transitioning from Army to Defense Health Program RDTE for further development. Noninvasive Neurodiagnostics TBI: The 3 technologies currently involve the Eye- Tracking System, the QEEG and Balance Platforms. None of these systems are anticipated to be ready at this time for transition to advanced development. Advanced Wound Dressing: Continuing to conduct comparative studies for the Advanced Wound Care commercial products (in-vivo animal or human studies). ***FY 2017 Plans:*** Oxygen Generator (15 LPM) System:will undergo airworthiness testing and will be procured with Army procurement (OPA) funds. Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Medical Equipment Sets Development: Will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment will be 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 improved technology will be developed to meet the user's need. Junctional / Noncompressible Hemorrhage Control Agent: Will complete studies to achieve a broader indication, improve device feasibility, increase shelf life, decrease unit price, and improve manufacturing efficiency..			
Title: Field Medical Systems Engineering Development PM Pharmaceuticals	10.294	14.978	13.583

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
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 2015 Accomplishments:*** Cryopreserved Platelets: The development schedule was extended one year due to the FDA requiring an additional safety clinical study. Began Phase 2 efficacy clinical trial in cancer patients with platelet deficiency and continued development of Phase 3 (expanded safety, efficacy and dosing) clinical testing and protocols for pivotal study. Freeze-Dried Plasma Program: Freeze Dried Plasma development effort terminated in FY13 with prime systems contractor due to bankruptcy. Schedule revised for new development effort to begin in FY14 and continued Phase 2b safety clinical study. ***FY 2016 Plans:*** Cryopreserved Platelets: 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. Continue development of Phase 3 (expanded safety, efficacy and dosing) clinical testing and protocols for pivotal study. Freeze-Dried Plasma Program: Continue the Phase 2 (safety and initial efficacy) clinical trials. Continue manufacturing development and validation of Freeze-Dried Plasma batches. ***FY 2017 Plans:*** Cryopreserved Platelets: Will continue the Phase 2 safety and 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 (expanded safety, efficacy and dosing) clinical testing and protocols for pivotal study. Will begin the manufacturing development and validation of Cryopreserved platelet batches. Freeze-Dried Plasma Program: Will continue the Phase 2 (safety and efficacy) clinical trials and prepare for Phase 3 clinical trial (confirming safety and efficacy in diverse populations). Will continue manufacturing development and validation of Freeze-Dried Plasma batches.			
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 Accomplishments:*** Pre-Hospital Medical Informatics Transport: Combat Developers validated requirements for the Pre-Hospital Medical Informatics Transport system. ***FY 2016 Plans:***	1.357	4.923	-

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
Pre-Hospital Medical Informatics Transport: Combat Developers begin the engineering and manufacturing development phase for the Pre-Hospital Medical Informatics Transport.			
Title: Field Medical Systems Engineering Development PM Medical Support Systems	3.223	1.868	6.823
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 2015 Accomplishments:*** Modernization of medical equipment sets: As part of the medical equipment sets, complete form, fit and function of field medical sink, continued to evaluate commercial litters, cold chain storage devices and commercial items. 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 air and ground medical evacuation. Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package: Continued 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): Completed operational testing of the Environmental Sentinel Biomonitor (ESB) and conducted 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 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): Completed 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: Developed 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: Began 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, complete evaluations of 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. Per Army Regulation 70-62, Airworthiness			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
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: 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): Finish Advanced Development of Environmental Sentinel Biomonitor with a MS C planned for early FY16 and transition product to procurement. Waste Treatment System for the CSH: Transition from Small Business Innovation Research in FY16 due to delays in development/ prototype evaluation. Start development of Waste Treatment System (WTS) for the Combat Support Hospital. Altitude Readiness Management System (ARMS): Transition the ARMS product to PEO Soldier and closeout the Advance Development effort. Improved Vector Trap: Continue prototype development of Vector Traps for user evaluation. Portable Vector Identification Workstation: Complete user evaluation of the field deployable vector identification workstation and add to Entomology Set. ***FY 2017 Plans:*** Modernization of medical equipment sets (MES): As part of the MES modernization, will evaluate the Combat Support Hospital water distribution system, environmental sampling devices, rodent collection/evaluation products, blood component freezers and commercial items. Airworthiness Testing: Will continue to conduct airworthiness testing for MES and Mission Essential Package (MEP) 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 MES, MEP, and CASEVAC: Will transition from project 836. Will finalize the MES and MEP in collaboration with Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for the Armored Multi-Purpose Vehicle Evacuation and Treatment platforms. Will work with PEO Combat Support/Service Support (CS & CSS) for development and testing of the CASEVAC system for the Joint Light Tactical Vehicle (JLTV). Waste Treatment System (WTS) for the CSH: Product will transition from Rapid Innovation Fund for developmental testing and user evaluation. Improved Flying Vector Trap (IFVT) (Formerly: Improved Vector Tent Traps): Will transition from PE 836. Will complete developmental and user testing of the IFVT. Soldier Optimization Decision Aids (SODA): Will develop and conduct Independent Validation and Verification and limited user testing of the Cold Weather Ensemble Decision Aid and Heat Strain Decision Aid; and prepare for networthiness certification and platform integration in collaboration with PEO Soldier for the Nett Warrior Platform. Hard-Walled Shelter Modernization (Radiation Panel): Will complete developmental and user testing of the Rigid Wall Shelter transportation and vibration modifications.			
Accomplishments/Planned Programs Subtotals	17.689	25.029	23.532

C. Other Program Funding Summary ($ in Millions)

N/A

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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*

C. Other Program Funding Summary ($ in Millions)

Remarks

D. Acquisition Strategy

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

E. Performance Metrics

N/A

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	27.719	2.483		1.867		3.917		-		3.917	Continuing	Continuing	Continuing
		Subtotal	27.719	2.483		1.867		3.917		-		3.917	-	-	-

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Freeze-dried Human Plasma	Various	HemCon Medical Technologies, Inc, : Tigard OR	32.750	-		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	4.118	1.124		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	1.200	1.784		0.359		1.220		-		1.220	0	4.563	0
Cryopreserved Platelets	Various	Multiple DoD activities and Dartmouth Hitchcock Med Ctr : North Potomac, MD	14.362	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	1.450	-		0.500		-		-		-	0	1.950	0
Intracellular Hemorrhage Treatment	TBD	TBD : TBD	0.000	-		0.750		-		-		-	0	0.750	0

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 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	0.373	-		-		-		-		-	0	0.373	0
Noninvasive Neurodiagnostics	TBD	TBD : TBD	0.000	2.647		-		-		-		-	0	2.647	0
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc. : Roseville, MN	0.000	0.335		4.747		-		-		-	0	5.082	0
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine)	TBD	TBD : TBD	0.000	0.950		1.586		4.629		-		4.629	0	7.165	0
Advanced wound care	Various	TBD : TBD	0.000	-		-		1.594		-		1.594	0	1.594	0
Junction Noncompressible Hemorrhage	TBD	RevMedX Inc : Wilsonville OR	0.000	-		-		1.550		-		1.550	0	1.550	0
		Subtotal	72.493	6.840		9.523		8.993		-		8.993	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 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		1.960		-		1.960	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various : Various	8.661	-		1.548		-		-		-	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various : Various	0.455	2.215		-		-		-		-	0	2.670	0
		Subtotal	14.673	2.874		1.855		1.960		-		1.960	-	-	-

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	14.408	-		1.615		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	TBD	TBD : TBD	1.150	1.743		6.101		4.865		-		4.865	0	13.859	0
Medical Equipment Sets Development	Various	Various : Various	0.114	1.092		-		-		-		-	0	1.206	0
Freeze Dried Plasma	C/CPFF	TBD : TBD	0.000	2.657		4.068		3.797		-		3.797	0	10.522	0
		Subtotal	15.672	5.492		11.784		8.662		-		8.662	-	-	-

	Prior Years	FY 2015		FY 2016		FY 2017 Base		FY 2017 OCO		FY 2017 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	130.557	17.689		25.029		23.532		-		23.532	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2017 Army		Date: February 2016
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*

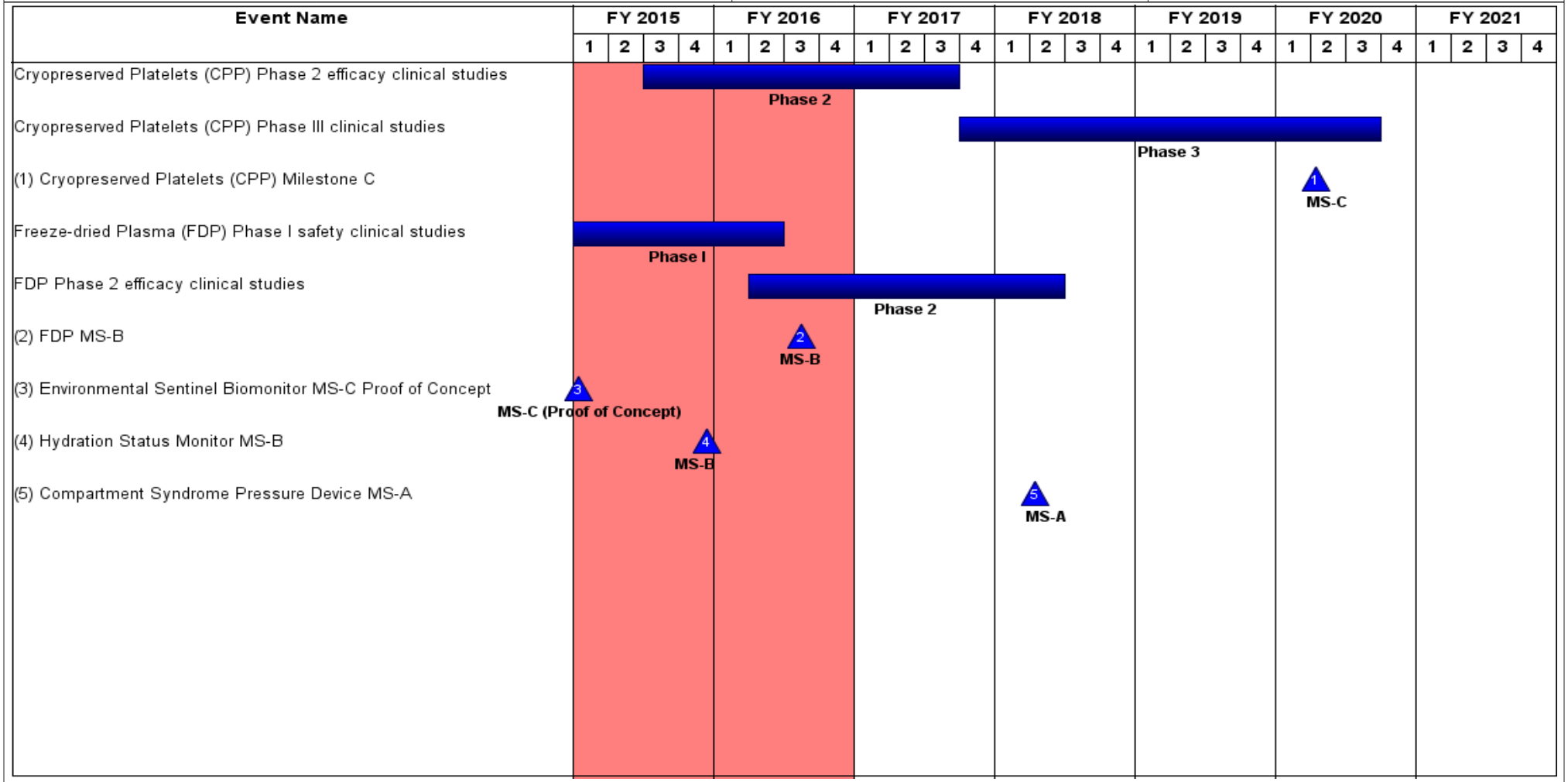

Exhibit R-4A, RDT&E Schedule Details: PB 2017 Army		Date: February 2016
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 832 / *Field Medical Systems Engineering Development*

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
Cryopreserved Platelets (CPP) Milestone C	2	2020	2	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
Hydration Status Monitor MS-B	4	2015	4	2015
Compartment Syndrome Pressure Device MS-A	2	2018	2	2018

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
849: *Infec Dis Drug/Vacc Ed*	-	10.310	14.953	12.922	-	12.922	13.171	14.821	16.437	16.875	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 2015	FY 2016	FY 2017
Title: Infectious Disease Drug and Vaccine Engineering Development	10.310	14.953	12.922
Description: Funding for research and development efforts for Drugs and Vaccines. ***FY 2015 Accomplishments:*** Dengue Tetravalent Vaccine (DTV): Continued patient follow up and completed Phase 3 (safety, efficacy, and dosing) pivotal clinical trials and adult/military-specific indication studies. Continued and completed follow up of Phase 2 military-specific / immunological evaluation study in Syracuse, NY. Developed a Biologic License Application (BLA) for US Licensure, developed Final reports, continued trial-related activities and data analysis. Validated Commercial Partner production of batches at their dedicated manufacturing facility. Next Generation Malaria Prophylaxis: Initiated New Drug Application (NDA) preparatory work for a supplemental NDA filing with commercial partner Glaxo-Smith Kline. Halted activities associated with a phase 3 (safety, efficacy, and dosing) studies that is no longer needed. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Transitioned from project 808 in FY14. Completed Phase 3 (safety, efficacy, and dosing) New World clinical trial in FY15 based on additional guidance and requirements from the FDA. Conducted MS-C decision review and submit New Drug Application to the FDA. Leishmania Rapid Diagnostic Device (LRDD): Completed fielding/delivery of Leishmania Rapid Diagnostic Device.			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
Antimalarial Drug, Artesunate Intravenous: Conducted MS-C decision review and submit New Drug Application to the FDA sent in FY14. Plan to obtain FDA approval in FY15 and began fielding/delivery of Antimalarial Drug, Artesunate Intravenous. 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. Infectious Disease Diagnostic products: Began field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever.			
FY 2016 Plans: Dengue Tetravalent Vaccine (DTV): Complete Phase 3 (safety, efficacy, and dosing) pivotal clinical trials and adult/military-specific indication studies. Submit the master file (product documentation) for endemic countries to the FDA. Complete Milestone C package. Develop Biologic License Application (BLA) for US Licensure. Final reports near completion for BLA submission in FY17 to the FDA. Commercial Partner to produce validation lots at their dedicated manufacturing facility. Next Generation Malaria Prophylaxis: Continue to complete New Drug Application preparatory work for filing with the FDA. 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): Complete the New Drug Application submission package and submit to the FDA for approval. Validate the manufacturing process for commercial production of the cream. Continue the expanded access and treatment protocols through FY 16. Antimalarial Drug, Artesunate Intravenous: Support FDA inquiries during the review process of the New Drug Application. Work 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. Diagnostic products: Delays in the previous year's transition for infectious disease diagnostic products due to product maturity. Begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever. Dengue Vaccine Block II: Prepare for human challenge efforts to show vaccine efficacy and animal studies			

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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 2015	FY 2016	FY 2017
to determine correlates of immunity in preparation for Phase III (safety, efficacy, and dosing) clinical trials. Arthropod Control/ Surveillance: Begin field testing and evaluation of a Dengue Rapid Diagnostic. ***FY 2017 Plans:*** Dengue Tetravalent Vaccine (DTV): Will continue to fund Block I Dengue Tetravalent Vaccine until FY18. Funding will cover the additional two-year volunteer follow-up and data analysis on pivotal Phase 3 safety and effectiveness clinical trials as well as analysis and submission of adult military/traveler phase 2 (safety and efficacy) data aimed toward FDA licensure (Key Performance Parameter) . Will continue to work with the commercial partner to support FDA submissions, marketing and distribution plans for the vaccine. Will start planning for potential MS C in FY17; fielding anticipated FY18. Next Generation Malaria Prophylaxis: Will continue to complete New Drug Application preparatory work for filing with the FDA. Will continue the retinal safety study started in FY16 and will prepare the protocols for required soldier specific studies that need to be completed. Will start planning for potential MS C in FY17. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): The planned submission of the New Drug Application (NDA) did not occur in FY16 due to the loss of a manufacturing subcontractor. The NDA submission package will be completed and submitted to the FDA for approval in FY17. The manufacturing process will be validated in preparation for commercial production of the cream. The expanded access treatment protocol will continue through FY 17. Antimalarial Drug, Artesunate Intravenous: Will continue to support FDA inquiries during the review process of the New Drug Application. Will continue to work with the commercial partner to support marketing and distribution plans for the drug. Infectious Disease Diagnostic products: In FY17 products within this area will move to the Rapid Diagnostic and Detection Devices. Development (clinical performance testing) of a rapid human dengue diagnostic device will be anticipated. Dengue Vaccine Block II: Development of additional dengue human challenge strains will continue. Evaluation of vaccine candidates through performance of dengue human challenge studies in preparation for Phase III (safety, efficacy, and dosing) clinical trials. Rapid Diagnostic and Detection Devices: Will continue field testing and evaluation of several product candidates to include: dengue, chikungunya and leptospirosis.			
Accomplishments/Planned Programs Subtotals	10.310	14.953	12.922

C. Other Program Funding Summary ($ in Millions)

N/A

Remarks

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.

Exhibit R-2A, RDT&E Project Justification: PB 2017 Army		Date: February 2016
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*

E. Performance Metrics

N/A

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	18.881	0.265		0.712		0.792		-		0.792	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	0.000	1.012		2.263		3.153		-		3.153	0	6.428	0
		Subtotal	18.881	1.277		2.975		3.945		-		3.945	-	-	-

Product Development ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various : Various	32.844	1.200		2.007		1.000		-		1.000	Continuing	Continuing	Continuing
Topical Antileishmanial Drug	TBD	TBD : TBD	2.400	-		-		-		-		-	0	2.400	0
Topical Antileishmanial Drug	C/TBD	Advantar Laboratories, INC : TBD	0.000	1.229		0.662		0.316		-		0.316	0	2.207	0
Dengue Tetravalent Vaccine	TBD	TBD : TBD	0.000	1.399		0.648		-		-		-	0	2.047	0
Hemorrhagic Fever W/ Renal Syndrome	C/TBD	TBD : TBD	0.000	-		1.000		-		-		-	0	1.000	0
		Subtotal	35.244	3.828		4.317		1.316		-		1.316	-	-	-

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	17.187	0.690		1.503		-		-		-	Continuing	Continuing	Continuing

Exhibit R-3, RDT&E Project Cost Analysis: PB 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 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		1.308		-		1.308	0	4.763	0
		Subtotal	17.187	3.858		1.790		1.308		-		1.308	-	-	-

Test and Evaluation ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	37.649	1.347		2.725		3.593		-		3.593	Continuing	Continuing	Continuing
Dengue Tetravalent Vaccine	TBD	WRAIR/AFRIMS : Silver Spring MD	0.000	-		-		0.881		-		0.881	0	0.881	0
Dengue Tetravalent Vaccine	C/TBD	TBD : TBD	0.000	-		-		1.879		-		1.879	0	1.879	0
Product Development of Dengue Tetravalent Vaccine	Various	TBD : TBD	1.384	-		3.146		-		-		-	0	4.530	0
		Subtotal	39.033	1.347		5.871		6.353		-		6.353	-	-	-

	Prior Years	FY 2015		FY 2016		FY 2017 Base		FY 2017 OCO		FY 2017 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	110.345	10.310		14.953		12.922		-		12.922	-	-	-

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2017 Army		Date: February 2016
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*

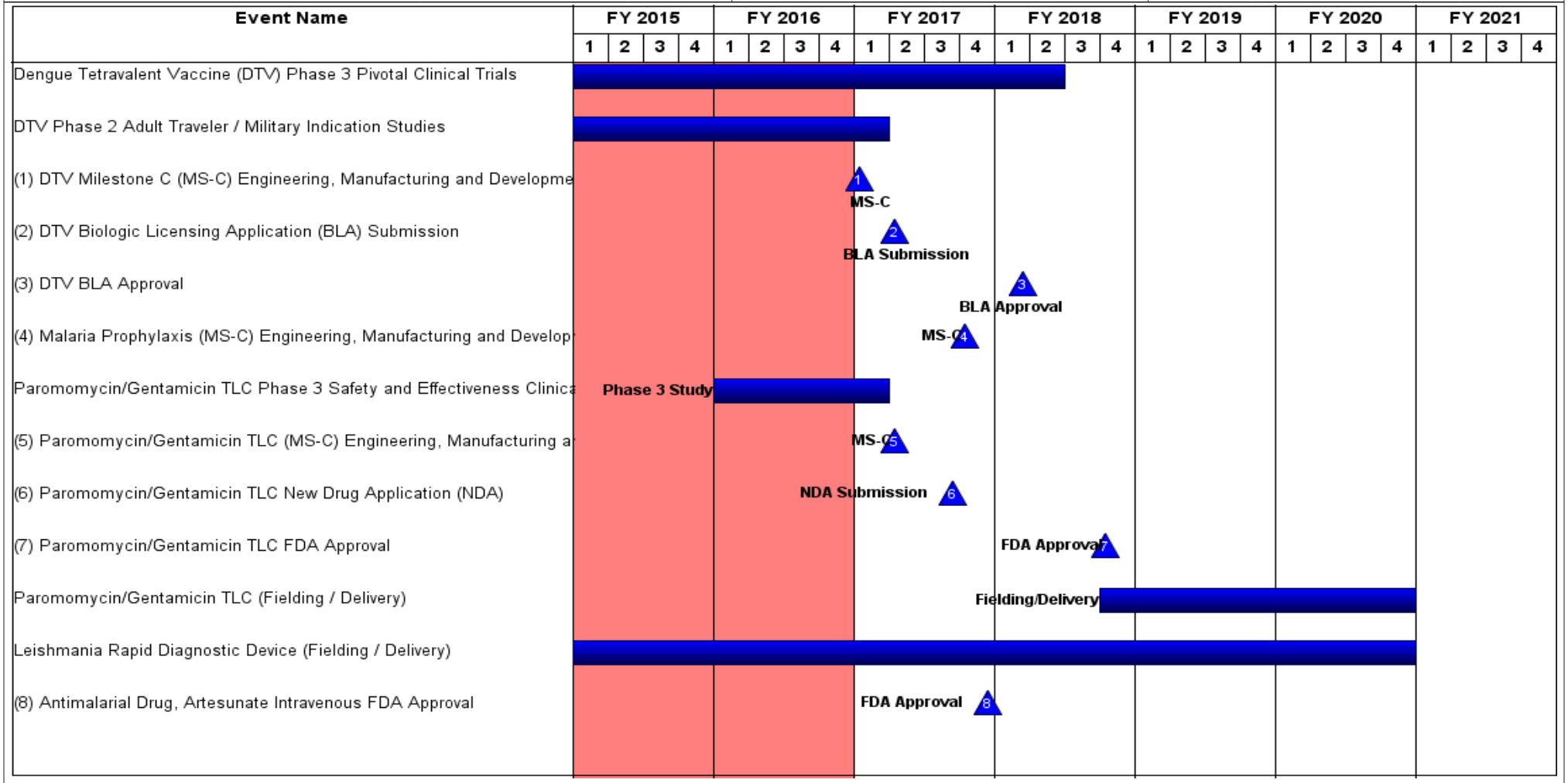

Exhibit R-4, RDT&E Schedule Profile: PB 2017 Army		Date: February 2016
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 849 / *Infec Dis Drug/Vacc Ed*

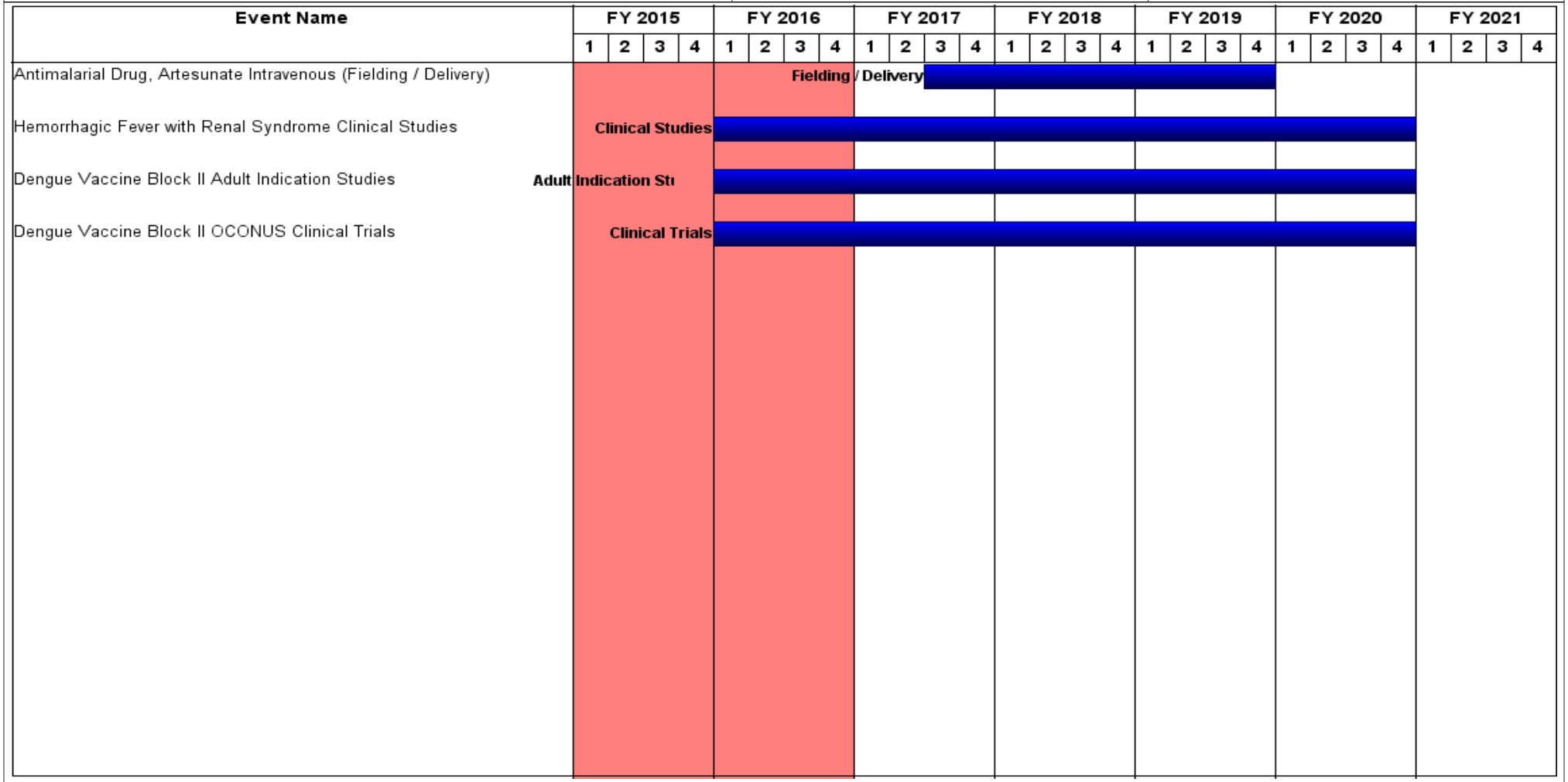

Exhibit R-4A, RDT&E Schedule Details: PB 2017 Army		Date: February 2016
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** 849 / *Infec Dis Drug/Vacc Ed*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials	1	2011	2	2018
DTV Phase 2 Adult Traveler / Military Indication Studies	2	2012	1	2017
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	1	2016	1	2017
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development	2	2017	2	2017
Paromomycin/Gentamicin TLC New Drug Application (NDA)	3	2017	3	2017
Paromomycin/Gentamicin TLC FDA Approval	4	2018	4	2018
Paromomycin/Gentamicin TLC (Fielding / Delivery)	4	2018	4	2020
Leishmania Rapid Diagnostic Device (Fielding / Delivery)	1	2015	4	2020
Antimalarial Drug, Artesunate Intravenous FDA Approval	4	2017	4	2017
Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)	3	2017	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 2017 Army			Date: February 2016
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 2015	FY 2016	FY 2017 Base	FY 2017 OCO	FY 2017 Total	FY 2018	FY 2019	FY 2020	FY 2021	Cost To Complete	Total Cost
VS8: *MEDEVAC Mission Equipment Package (MEP) - End Dev*	-	0.000	0.399	0.113	-	0.113	0.114	0.000	0.000	0.000	Continuing	Continuing
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

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 2015	FY 2016	FY 2017
Title: Interim MEDEVAC Mission Support System (IMMSS)	-	0.399	0.113
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. Develop plans for required validation and verification to address the new paramedic skills. ***FY 2017 Plans:*** Interim MEDEVAC Mission Support System (IMMSS): Will complete validation study to verify IMMSS supports Medical Evacuation En Route Care.			
Accomplishments/Planned Programs Subtotals	-	0.399	0.113

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 2017 Army		Date: February 2016
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 2017 Army			Date: February 2016
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 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 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	2.120	0
		Subtotal	1.721	-		0.399		-		-		-	0.000	2.120	0.000

Support ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	SS/UCA	Redstone Arsenal : AL	0.621	-		-		-		-		-	0	0.621	0
		Subtotal	0.621	-		-		-		-		-	0.000	0.621	0.000

Test and Evaluation ($ in Millions)

Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
IMMSS test and evaluation	TBD	Redstone Arsenal : AL	0.000	-		-		0.113		-		0.113	0	0.113	0
		Subtotal	0.000	-		-		0.113		-		0.113	0.000	0.113	0.000

	Prior Years	FY 2015 Cost	FY 2015 Award Date	FY 2016 Cost	FY 2016 Award Date	FY 2017 Base Cost	FY 2017 Base Award Date	FY 2017 OCO Cost	FY 2017 OCO Award Date	FY 2017 Total Cost	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	2.342	-		0.399		0.113		-		0.113	0.000	2.854	0.000

Remarks

Exhibit R-4, RDT&E Schedule Profile: PB 2017 Army		Date: February 2016
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*

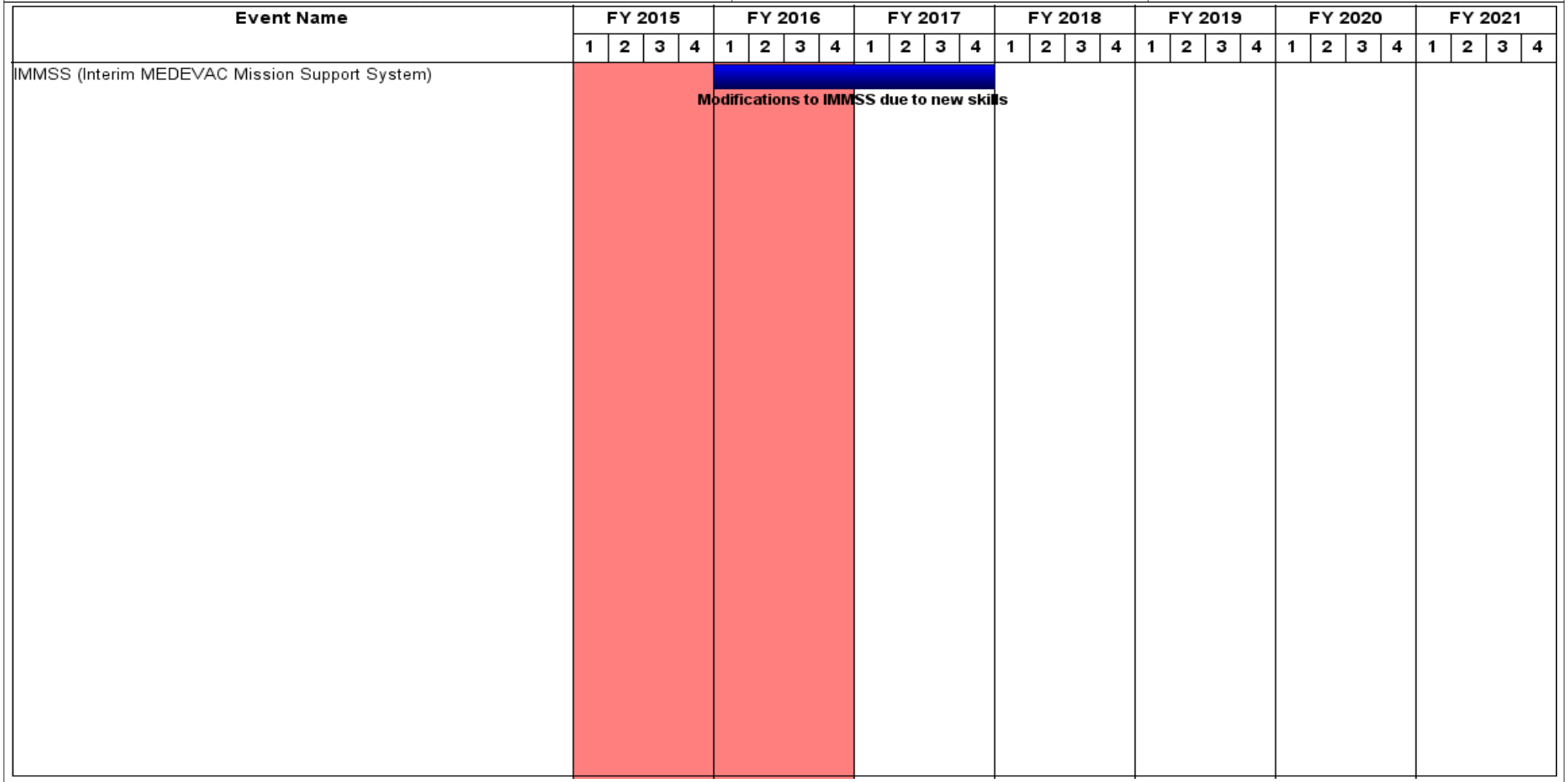

Exhibit R-4A, RDT&E Schedule Details: PB 2017 Army		Date: February 2016
Appropriation/Budget Activity 2040 / 5	**R-1 Program Element (Number/Name)** PE 0604807A / *Medical Materiel/Medical Biological Defense Equipment - Eng Dev*	**Project (Number/Name)** VS8 / *MEDEVAC Mission Equipment Package (MEP) - End Dev*

Schedule Details

	Start		End	
Events	**Quarter**	**Year**	**Quarter**	**Year**
IMMSS (Interim MEDEVAC Mission Support System)	1	2016	4	2017

Note

Modifications to IMMSS based on new approved paramedic skills for medical personnel

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