

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

May 2009

BUDGET ACTIVITY	PE NUMBER AND TITLE				
<b>5 - System Development and Demonstration</b>	<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>				
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	23397	45222	33893	Continuing	Continuing
812 MIL HIV VAC&DRUG DEV	4506	4681	4472	Continuing	Continuing
832 Field Medical Systems Engineering Development	4880	14804	15716	Continuing	Continuing
834 SOLDIER SYS PROT-ED	1793	1777		Continuing	Continuing
849 INFEC DIS DRUG/VACC ED	3909	13594	13705	Continuing	Continuing
A11 LSTAT MEDICAL TECHNOLOGY (CA)	3092	2392			5484
CS5 MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)	5217	7974			13191

**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 phase through completion of the Milestone C Decision Review. When available, commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the US Food and Drug Administration, along with related product stability, production manufacturing, supportability analysis, and operational testing for biologics (products derived from living organisms) and devices to demonstrate that products are safe and effective.

Combat Casualty Care devices and medicines: (1) enhance care at the first responder level to save lives, and (2) provide more effective post evacuation medical care and rehabilitation to shorten recovery time. The F2 concept places Soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). This requires medics and first responders to improve their ability to save lives and extend stabilization. Reduction in weight, cube, and sustainment allows medical units to increase mobility and maintain contact with their supported Units of Action.

Soldier performance enhancers in the form of drugs or diagnostics, allow commanders to increase Soldiers cognitive awareness and stamina. This improves Soldiers operational capabilities and has the potential to reduce casualties.

Disease and non-battle injuries (DNBI) are the largest contributor to the medical footprint. Infectious disease vaccines and preventive drugs reduce the risk of warfighters contracting debilitating or fatal diseases, reducing levels of DNBI affected Soldiers and in turn, significantly reducing a large portion of the requirement for supporting combat support hospitals in the theater of operations, and the strain placed on the Army's personnel replacement and logistical systems. This is especially important due to the higher risk posed by the ever expanding urban warfare environments. The reduction of patient evacuation requirements within the current and Future Force (F2) units will act as a force multiplier, due to the retention of uniquely skilled and combat tested Soldiers in the theater.

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

May 2009

BUDGET ACTIVITY

**5 - System Development and Demonstration**

PE NUMBER AND TITLE

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

Military Human Immunodeficiency Virus (HIV) Vaccine and Drug Development funds militarily relevant HIV medical countermeasures. These include advanced component development of candidate vaccines and drugs for large-scale field testing.

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.

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

May 2009

**BUDGET ACTIVITY**  
**5 - System Development and Demonstration**

**PE NUMBER AND TITLE**  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev**

<u><b>B. Program Change Summary</b></u>	FY 2008	FY 2009	FY 2010
Previous President's Budget (FY 2009)	27745	34971	33613
Current BES/President's Budget (FY 2010)	23397	45222	33893
Total Adjustments	-4348	10251	280
Congressional Program Reductions	-178	-149	
Congressional Rescissions			
Congressional Increases		10400	
Reprogrammings	-3413		
SBIR/STTR Transfer	-757		
Adjustments to Budget Years			280

Change Summary Explanation: Funding:  
 In FY08 \$3.413 million reprogrammed to 6.3 funding for Plasma Sterilizer and Vet Research Manpower Project.  
 In FY09, increase of \$10.4 million was due to Congressional ads to the following projects:  
 In FY09 project Rotary Valve Pressure Sing Absorption Oxygen Generator received \$800 thousand.  
 In FY09 project Plasma Sterilizer received \$3.2 million.  
 In FY09 project Lightweight Trauma Model received \$2.4 million.  
 In FY09 project Pharmaceutical Advanced Packaging received \$1.6 million.  
 In FY09 project LSTAT Advanced Medical Technologies received \$2.4 million.

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>812</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
812 MIL HIV VAC&DRUG DEV	4506	4681	4472	Continuing	Continuing

**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><u>Accomplishments/Planned Program:</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>	<b><u>FY 2010</u></b>
In FY08, continued the observation and follow-up phase of the multi-year expanded safety/efficacy trial in Thailand. In FY09, complete the observation and follow-up phase of the expanded safety/efficacy trial (> 16,000 subjects) in Thailand and begin data analysis for this HIV Vaccine (conduct Design Readiness Review (DRR). In FY10, prepare preliminary clinical study report on the completed expanded safety/efficacy trial in Thailand and conduct a critical design review (CDR) to determine future development of the prime-boost vaccine based on trial results. Follow up clinical trial for HIV positive for viral load in order to validate viral load as a surrogate endpoint for use in HIV vaccine studies.	4506	4550	4472
Small Business Innovative Research/Small Business Technology Transfer Programs.		131	
<b>Total</b>	<b>4506</b>	<b>4681</b>	<b>4472</b>

**B. Other Program Funding Summary** Not applicable for this item.

**C. Acquisition Strategy** Test and evaluate commercially developed vaccine candidates in government-managed trials.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>								<b>812</b>	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	15280	3153		3326		3247			28253	
Subtotal:			15280	3153		3326		3247			28253	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			394	46		47		46			579	
Subtotal:			394	46		47		46			579	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	4950	1213		1213		1088			8464	
Subtotal:			4950	1213		1213		1088			8464	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>			PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>						PROJECT <b>812</b>	
No product/contract costs greater than \$1M individually			483	94		95		91		854
Subtotal:			483	94		95		91		854
<b>Project Total Cost:</b>										
			<b>21107</b>	<b>4506</b>		<b>4681</b>		<b>4472</b>		<b>38150</b>

# Schedule Profile (R4 Exhibit)

May 2009

**BUDGET ACTIVITY**  
**5 - System Development and Demonstration**

**PE NUMBER AND TITLE**  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev**

**PROJECT**  
**812**

Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Prime-Boost HIV Vaccine (DRR)								0																								
HIV Vaccine (CDR)												0																				



**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>						PROJECT <b>812</b>
<u>Schedule Detail</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>
Prime-Boost HIV Vaccine (DRR)		4Q						
HIV Vaccine (CDR)			4Q					

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>832</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
832 Field Medical Systems Engineering Development	4880	14804	15716	Continuing	Continuing

**A. Mission Description and Budget Item Justification:** This project funds 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 efficacy of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Mature commercially-off-the-shelf (COTS) medical products are also evaluated for military use. Consideration will also be 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.

In FY10, Project 834 Soldier Sys Prot-ED will be consolidated into Project 832.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; SeQual Technologies, Inc.; Enginivity, Inc.; Ultrasound Diagnostics, Inc.; HemCon Medical Technologies, Inc.; 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.

<b><u>Accomplishments/Planned Program:</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>	<b><u>FY 2010</u></b>
(1) Ceramic Oxygen Generator (COG): In FY09, transition from project 836, conduct technical and user evaluations, obtain FDA clearance, conduct a Milestone C review in Qtr 3 FY 09 and transition to Production and Deployment. (2) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY08 transitioned from project 836 and conducted user testing and evaluation of Omni II system. In FY09, conduct Milestone C review of Omni II, and initiate low rate production, with an estimated completion of Qtr 4 FY 09.(3) Battery Powered IV Fluid Warmer: In FY08, developed battery prototype to replace line power. In Qtr 4 FY 09 conduct a Milestone C review and transition to Production and Deployment.(4) Field Sterilizer: In FY09, following multiple vendor review, conduct technical and user evaluation to determine the best solution. (5) 120 LPM (liter per minute) Oxygen Generator: In FY09, begin request for proposal for review of production capabilities - performance characteristics will be reviewed to determine if a commercial-off-the-shelf (COTS) solution can meet current capabilities defined or if research and development refinement of a COTS system is feasible .(6) Ultrasonic Brain Imager (UBI): In FY10, transition from project 836, begin safety and effectiveness human clinical trial, conduct a human factor evaluation of the prototype, and conduct a Milestone C for transition to Production and Deployment. (7) Freeze-dried Plasma Program: In FY09, transition from project 836 and based on a down-select, manufacture clinical lots of a freeze-dried plasma product, and begin pre-trial activities for a safety/efficacy human clinical trial. In FY10, begin a multi-center safety/efficacy human clinical trial, and perform stability studies on the product.	4880	14393	15716
(8) Red Blood Cell Extended Life (RBCXL) program (severe bleeding treatment candidate - a new blood collection and storage system			

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

May 2009

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT	
<b>5 - System Development and Demonstration</b>	<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>	<b>832</b>	
<p>that extends the shelf-life of red blood cells from 6 to 8 weeks): In FY09 transition from 836 and begin a human safety/efficacy study, and perform good manufacturing practices validation of the blood collection and storage system. In FY10, will prepare and complete enrollment in a human safety/efficacy study. (9) Platelet Derived Hemostatic Agent (PDHA): (10) Intranasal Ketamine (low dose pain management via nasal spray): (11) Hypertonic Saline Dextran (treatment of shock due to blood loss): In FY10 will support human expanded safety/efficacy trial for treatment of shock. (12) Woundstat Safety Study: In FY09, complete testing and move to production. (13) Lab, Blood Bank, and Anatomical testing for COTS equipment to meet essential characteristics and enhance technology. Testing to begin Qtr 1 FY09. (14) Dental Field Unit: In FY09, begin and complete request for proposal for review of production capabilities - performance characteristics will be reviewed to determine if a commercial-off-the-shelf (COTS) solution can meet current capabilities defined or if research and development refinement of a COTS system is feasible.</p>			
<p>(15) Noise Immune Stethoscope: In 4Q FY09, transition from project 879, and secure FDA Approval, Meet Ruggedness Requirements, Establish Manufacturing Practice, Set Up Manufacturing. Conduct Milestone C in FY09. (16) Life Support for Trauma and Transport (LSTAT): In FY10, transition from project 834, conduct Milestone C 3Q and transition to Production and Deployment. (17) In FY10, conduct air worthiness testing on commercial off the shelf and non-developmental medical devices for military field use.</p>			
Small Business Innovative Research/Small Business Technology Transfer Programs.		411	
Total		4880	15716

**B. Other Program Funding Summary** Not applicable for this item.

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

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>								<b>832</b>	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Rotary Valve Pressure Swing Adsorption oxygen Generator		Sequal Technologies, Inc., San Diego, CA	3197	4880		300					8377	
Hypertonic Saline Dextran		National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI) Bethesda, MD						4800			4800	
Freeze-dried Human Plasma		HemCon Medical Technologies, Inc, Tigard, OR				3255		7150			10905	
Extended Life Red Blood Cell Product		Hemerus Medical, LLC, St. Paul, MN				1150		745			1895	
Virtual Imaging						1000		450			1450	
No product/contract costs greater than \$1M individually						1260					1260	
Subtotal:			3197	4880		6965		13145			28687	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Regulatory Support		Clinical Research Management, Inc., Hinckley, OH				1357		1400			4157	
						1808		234			4396	
Subtotal:						3165		1634			8553	

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY  
**5 - System Development and Demonstration**

PE NUMBER AND TITLE PROJECT  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev 832**

III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Not Applicable						3046		433			7587	
Subtotal:						3046		433			7587	

IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			18173			1628		504		Cont.	Cont.	
Subtotal:			18173			1628		504		Cont.	Cont.	

<b>Project Total Cost:</b>			<b>21370</b>	<b>4880</b>		<b>14804</b>		<b>15716</b>		<b>Cont.</b>	<b>Cont.</b>	
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# Schedule Profile (R4 Exhibit)

May 2009

**BUDGET ACTIVITY**  
**5 - System Development and Demonstration**

**PE NUMBER AND TITLE**  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev**

**PROJECT**  
**832**

Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15				
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	
(1) Ceramic Oxygen Gen Sys (MS-C)								▲ 0	MS C																								
(2) Rotary Valve Press Swing Oxy (MS-C)								▲ 0	MS C																								
(3) Battery Powered Iv Fld Warm (MS-C)								▲ 0	MS C																								
(4) Field Sterilizer (MS-B)								▲ 0	MS B																								
(6) Ultrasonic Brain Imager (MS-C)												▲ 0	MS C																				
(7) Freeze-dried Human Plasma - clinical lots																▲ 0																	
(8) Red Blood Cell Extend Life - submit for FDA approval																				▲ 0													
(14) Noise Immune Stethoscope, (MS-C)																																	
(15) Life Support for Trauma and Transport (LSTAT) (MS-C)																																	



## Schedule Detail (R4a Exhibit)

May 2009

BUDGET ACTIVITY		PE NUMBER AND TITLE						PROJECT
<b>5 - System Development and Demonstration</b>		<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>						<b>832</b>
<u>Schedule Detail</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>
Ventilatory Assist Device (MS-C)		2Q						
(1) Ceramic Oxygen Gen Sys (MS-C)		3Q						
(2) Rotary Valve Press Swing Oxy (MS-C)		4Q						
(3) Battery Powered Iv Fld Warm (MS-C)		4Q						
(4) Field Sterilizer (MS-B)		4Q						
(6) Ultrasonic Brain Imager (MS-C)			2Q					
(7) Freeze-dried Human Plasma - clinical lots			3Q - 4Q	1Q - 4Q				
(8)Red Blood Cell Extend Life - submit for FDA approval				2Q - 4Q				
(14) Noise Immune Stethoscope, (MS-C)		4Q						
(15) Life Support for Trauma and Transport (LSTAT) (MS-C)			4Q					
Cartledge Infuser (MS-C)	4Q							

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>834</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED	1793	1777		Continuing	Continuing

**A. Mission Description and Budget Item Justification:** This project funds system development and demonstration of preventive medicine materiel, to include devices and medicines, in order to provide protection, sustainment, and enhancement of the physical and psychological capabilities of Soldiers engaged in combat operations across environmental conditions. The focus is on reduction of personnel losses due to preventable disease and non-battle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures.

In FY10, Project 834 will be consolidated into Project 832 Combat Medical Matl ED.

Major contractors/performers are Pacific Technologies, Inc, Redwood, WA; Integrated Medical Systems, Inc, Signal Hill, CA, and the U.S. Army Aeromedical Research Laboratory, Fort Rucker, AL.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Coliform Analyzer: In FY09, transition from project 837, performed operational testing, conduct Milestone C 4Q, and transition to Production and Deployment. Special Medical Emergency Evacuation Device (SMEED): In 4Q FY 08, conducted Milestone C and transitioned to Production and Deployment. Life Support for Trauma and Transport (LSTAT): In FY08, completed design validation testing of LSTAT-Lite. In FY09, complete development of LSTAT-Lite, produce test articles, and conduct airworthiness, operational, and environmental testing. In FY10, transition to project 832. In FY08 and FY09, conduct air worthiness testing on commercial off the shelf and non-developmental medical devices for military field use.	1793	1726	
Small Business Innovative Research/Small Business Technology Transfer Programs		51	
<b>Total</b>	<b>1793</b>	<b>1777</b>	

**B. Other Program Funding Summary** Not applicable for this item.

**C. Acquisition Strategy** Test and evaluate in-house and commercially developed preventative medicine materiel to meet FDA and EPA regulatory requirements.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>							<b>834</b>		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			3688	853		826					5367	
Congressional Add in Support of Chem-Bio Protection			4550								4550	
Subtotal:			8238	853		826					9917	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			163	56		54					273	
Subtotal:			163	56		54					273	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			1046	302		341					1689	
Subtotal:			1046	302		341					1689	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>			PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>							PROJECT <b>834</b>	
No product/contract costs greater than \$1M individually			1792	582		556				2930	
Subtotal:			1792	582		556				2930	
<b>Project Total Cost:</b>			<b>11239</b>	<b>1793</b>		<b>1777</b>				<b>14809</b>	

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY  
**5 - System Development and Demonstration**

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev**

PROJECT  
**834**

Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Coliform Analyzer (MS C)								0 ▲																								
Special Medical emergency Evacuation Device (SMEED) (MS-C)				MS C 0 ▲																												



**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>						PROJECT <b>834</b>
<u>Schedule Detail</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>
Coliform Analyzer (MS C)		4Q						
Special Medical emergency Evacuation Device (SMEED) (MS-C)	4Q							

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>849</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
849 INFECDIS DRUG/VACC ED	3909	13594	13705	Continuing	Continuing

**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 insect control measures to limit exposure and disease transmission. It funds research that supports conclusive human clinical trials for large-scale human efficacy 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.

<u>Accomplishments/Planned Program:</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Clinical trials, developmental testing, and reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents: In FY08, for the Malaria Rapid Diagnostic Device (MRDD) program, Binax, Inc. (industry partner) submitted a request to the FDA for marketing approval, for an accessory kit to be used with the MRDD to comply with good laboratory practices. For Tafenoquine (anti-malarial drug), began pre-trial planning for a malaria study in humans to obtain blood samples for use with development/validation of a laboratory-based surrogate marker assay; and conducted the Combined Camouflage Face Paint/Insect Repellent (CCFP) pilot phase of the Soldier acceptability clinical trial. In FY09, for Tafenoquine, begin enrollment in a small human clinical challenge trial exposing volunteers to the malaria parasite (using current FDA-approved malaria drug mefloquine) to gather a baseline of the human body's immune responses to malaria and collect blood samples to be used in the validation of a laboratory assay to be used as a tool to determine the rate of malaria infection. For CCFP, complete the Soldier acceptability clinical study, finalize the study report, and conduct a Milestone C for transition to Production and Deployment. In FY10, for Tafenoquine, will conduct data analysis and prepare a final report on the small human challenge clinical trial, and will begin pre-trial activities for a large-scale safety/efficacy human clinical trial (treatment indication) in a malaria endemic country.	2007	2725	3891
Clinical trials, developmental testing, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis (a skin-based disease caused by a parasite and transmitted by sand flies), Dengue (a severe debilitating disease caused by a virus and transmitted by a mosquito), and other viral diseases): In FY08, continued monitoring industry partner's Hepatitis E vaccine effort; for the Dengue Tetravalent Vaccine (DTV), continued vaccine potency and stability testing and supported pre-trial activities in Thailand for an expanded safety and efficacy human clinical trial; and for the Paromomycin/Gentamicin Topical Antileishmanial Cream (for treatment of cutaneous (skin) leishmaniasis), began preparing the FDA licensure submission package and continued stability testing of drug lots. In FY09, for	1902	10511	9814

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Topical Antileishmanial Cream, transition from project 808 the overseas human clinical trial activities to continue enrollment in the Tunisian large scale (> 300 subjects) pivotal human safety/efficacy treatment trial, will begin enrollment in three small (<35 subjects) pharmacokinetic (drug metabolism) human trials in France, Peru and Panama, and prepare for a second large scale (> 300 subjects) human trial in Central/South America. For Pentostam (intravenous drug treatment of skin lesions caused by the Leishmania parasite), continue medical consult and database management in support of the industry partner's FDA licensure submission efforts. For the DTV vaccine, transition from project 808 the overseas human clinical trial activities to complete enrollment and continue monitoring the expanded human safety and immunity trial in Puerto Rico, complete data analysis in the human safety and immune response trial (adults) in the U.S., complete subject follow-up for the expanded human safety and immune response trials (three trials: infant, children and adult) in Thailand, and begin preliminary data analysis, and continue pre-trial planning for an expanded safety and			
efficacy trial in children in Thailand, For Hepatitis E vaccine, continue maintenance of study blood specimens kept under cold storage and monitoring of industry partner's Hepatitis E vaccine development effort. In FY10, Topical Antileishmanial Cream, will continue subject enrollment/follow-up in the Tunisia large scale (> 300 subjects) human safety/efficacy trial and will begin the second large scale human safety/efficacy trial in Central/South America, and complete the three small scale (<35 subjects) pharmacokinetic (drug metabolism) human trials in France, Peru and Panama. For Pentostam, monitor progress of industry partner's FDA licensure submission efforts. For Dengue Tetravalent Vaccine, will complete subject follow-up and begin the data analysis on the expanded human safety and immunity trial in Puerto Rico, will complete the study report on the human safety and immune response trial (adults) in the U.S., will complete the study reports (infant, children and adult) on the expanded human safety and immune response trial in Thailand, and will complete pre-trial activities for the expanded safety and efficacy trial in children in Thailand. For Hepatitis E vaccine, continue maintenance of study blood specimens kept under cold storage and monitoring of industry partner's Hepatitis E vaccine development effort.			
Small Business Innovative Research/Small Business Technology Transfer Programs.		358	
<b>Total</b>	<b>3909</b>	<b>13594</b>	<b>13705</b>

**B. Other Program Funding Summary** Not applicable for this item.

**C. Acquisition Strategy** Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>							<b>849</b>		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			8389	1369		3399		3480		Cont.	Cont.	Cont.
Subtotal:			8389	1369		3399		3480		Cont.	Cont.	Cont.
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			595	81		2719		2783		Cont.	Cont.	Cont.
Subtotal:			595	81		2719		2783		Cont.	Cont.	Cont.
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			12265	1800		5030		4936		Cont.	Cont.	Cont.
Subtotal:			12265	1800		5030		4936		Cont.	Cont.	Cont.
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			3592	659		2446		2506		Cont.	Cont.	Cont.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>	PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>						PROJECT <b>849</b>		
Subtotal:	3592	659		2446		2506	Cont.	Cont.	Cont.
<b>Project Total Cost:</b>	<b>24841</b>	<b>3909</b>		<b>13594</b>		<b>13705</b>	<b>Cont.</b>	<b>Cont.</b>	<b>Cont.</b>

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY  
**5 - System Development and Demonstration**

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev**

PROJECT  
**849**

Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Combination Camouflage Face Paint/Insect Repellent (MS-C)					MS-C 																											



**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>	PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>	PROJECT <b>849</b>
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<u>Schedule Detail</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014</u>	<u>FY 2015</u>
Combination Camouflage Face Paint/Insect Repellent (MS-C)		4Q						
Paromomycin/Gentamicin Topical Antileishmanial Cream (CDR)								

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>A11</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
A11 LSTAT MEDICAL TECHNOLOGY (CA)	3092	2392			5484

**A. Mission Description and Budget Item Justification:** The LSTAT is a life support piece of combat medical equipment. It is a litter with imbedded life support equipment, which is capable of sustaining an injured soldier for an extended period of time. This equipment will allow a soldier to be transported while maintaining all medical surveillance and diagnostics continually intact.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Congressional Add	3092	2325	
Small Business Innovative Research/Small Business Technology Transfer Program		67	
<b>Total</b>	<b>3092</b>	<b>2392</b>	

**B. Other Program Funding Summary** Not applicable for this item.

**C. Acquisition Strategy** Not applicable for this item.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>								<b>A11</b>	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract cost greater than \$1M individually			2078	3092		2392					7562	
Subtotal:			2078	3092		2392					7562	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
<b>Project Total Cost:</b>			<b>2078</b>	<b>3092</b>		<b>2392</b>					<b>7562</b>	

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**May 2009**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>	<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>			<b>PROJECT</b> <b>CS5</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
CS5 MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)	5217	7974			13191

**A. Mission Description and Budget Item Justification:** Congressional Interest Item funding for medical materiel/medical biological Defense initiatives

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Congressional add	5217	7751	
Small Business Innovative Research/Small Business Technology Transfer program		223	
Total	5217	7974	

**B. Other Program Funding Summary** Not applicable for this item.

**C. Acquisition Strategy** Not applicable for this item.