

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

February 2007

BUDGET ACTIVITY		PE NUMBER AND TITLE								
<b>5 - System Development and Demonstration</b>		<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>								
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	15890	24536	15823	35190	33842	15588	17336	17745		179689
812 MIL HIV VAC&DRUG DEV	3931	4511	4665	4727	4573	4573	4570	4676		36226
832 COMBAT MEDICAL MATL ED	756	3721	5275	14947	14277	5494	6217	6364		57051
834 SOLDIER SYS PROT-ED		2979	1856	1795	1698	1691	1789	1832		13640
849 INFEC DIS DRUG/VACC ED	565	3139	4027	13721	13294	3830	4760	4873		48209
A11 LSTAT MEDICAL TECHNOLOGY (CA)	1916	2176								5819
A12 BIOMEDICAL ENGINEERING TECH & ADV MATERIALS (CA)	4505	3560								8065
A14 CHITOSAN BANDAGE COMPONENT (CA)	3258	4450								9720
MD3 CARTLEDGE INFUSER	959									959

**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. It supports products successfully transitioned through the Systems Development and Demonstration In-Process Review (IPR). This largely includes Phase 3 human clinical trials, along with related stability and production manufacturing testing for medical pharmaceuticals, biologics, and devices. Added operational testing and evaluation (OT&E) for military unique requirements is evaluated and fulfilled as required.

Disease and non-battle injuries (DNBI) are the largest contributor to the medical footprint. Infectious disease vaccines and preventive drugs reduce the risk of service members contracting debilitating or fatal diseases, which reduces levels of DNBI affected soldiers and in turn, negates the requirement for supporting echelon 3 facilities in the theater of operations, as well as mitigates 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 Future Force (F2) units will act as a force multiplier, due to the retention of uniquely skilled and combat tested soldiers in the theater.

Combat Casualty Care devices and medicines have the major effects of: (1) enhancing forward care at the first responder level and, (2) reducing the medical footprint. The result is a far greater mobile and more easily sustained medical force. 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.

The U.S. Army Medical Research and Materiel Command manages this program.

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

February 2007

BUDGET ACTIVITY

PE NUMBER AND TITLE

**5 - System Development and Demonstration**

**0604807A - Medical Materiel/Medical Biological Defense Equipm**

Project 812, Military HIV Vaccine and Development funds militarily relevant human immunodeficiency virus (HIV) research.

Major contractors/intra-governmental agencies include Allied Technologies & Consulting, IGR Enterprises, Army Medical Department Board Test Center, and SeQual Technologies, Inc.

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

February 2007

BUDGET ACTIVITY	PE NUMBER AND TITLE			
<b>5 - System Development and Demonstration</b>	<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>			
<b><u>B. Program Change Summary</u></b>	FY 2006	FY 2007	FY 2008	FY 2009
Previous President's Budget (FY 2007)	16487	14509	15934	35243
Current BES/President's Budget (FY 2008/2009)	15890	24536	15823	35190
Total Adjustments	-597	10027	-111	-53
Congressional Program Reductions		-94		
Congressional Rescissions				
Congressional Increases		10300		
Reprogrammings	-597	-179		
SBIR/STTR Transfer				
Adjustments to Budget Years			-111	-53

FY 2007 - Congressional Plus-Up (\$10,300) - LSTAT Medical Technology (\$2,200); Biomedical Engineering Technology and Advanced Materiel (\$3,600); and Chitosan Bandage Component (\$4,500).

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

**February 2007**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>		<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							<b>PROJECT</b> <b>812</b>	
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	Cost to Complete	Total Cost
812 MIL HIV VAC&DRUG DEV	3931	4511	4665	4727	4573	4573	4570	4676		36226

**A. Mission Description and Budget Item Justification:** This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of multiple candidate vaccines and drugs to permit large-scale field testing. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment.

The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD.

<b>Accomplishments/Planned Program:</b>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Reviews, evaluations and trials of Human Immunodeficiency Virus (HIV) Vaccine: In FY06, completed immunizations and entered the observation and follow-up phase of the multi-year Phase 3 clinical trial of the Prime-Boose HIV Vaccine in Thailand. In FY07, continue the observation and follow-up phase of the Phase 3 study in Thailand and conduct a Design Readiness Review. In FY08, continue the observation and follow-up phase of the Phase 3 trial in Thailand. In FY09, complete the observaton and follow-up phase of the Phase 3 trial in Thailand and begin data analysis.	3931	4384	4665	4727
Small Business Innovative Research/Small Business Technology Transfer Programs.		127		
<b>Total</b>	3931	4511	4665	4727

**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)

February 2007

BUDGET ACTIVITY			PE NUMBER AND TITLE									PROJECT		
5 - System Development and Demonstration			0604807A - Medical Materiel/Medical Biological Defense Equipm									812		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	6930	2791		3203		3312		3356			19592	
Subtotal:			6930	2791		3203		3312		3356			19592	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			271	39		45		46		47			448	
Subtotal:			271	39		45		46		47			448	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 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	1733	1022		1173		1213		1229			6370	
Subtotal:			1733	1022		1173		1213		1229			6370	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater			235	79		90		94		95			593	

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>				PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							PROJECT <b>812</b>	
than \$1M individually												
Subtotal:				235	79		90		94		95	593

<b>Project Total Cost:</b>				<b>9169</b>	<b>3931</b>		<b>4511</b>		<b>4665</b>		<b>4727</b>	<b>27003</b>
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# Schedule Profile (R4 Exhibit)

February 2007

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

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipm**

PROJECT  
**812**

Event Name	FY 06				FY 07				FY 08				FY 09				FY 10				FY 11				FY 12				FY 13			
	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) HIV Vaccine Design Readiness Review (DRR)					▲																											

**Schedule Detail (R4a Exhibit)**

**February 2007**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>					PROJECT <b>812</b>	
<u>Schedule Detail</u>	<u>FY 2006</u>	<u>FY 2007</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>
HIV Vaccine Design Readiness Review (DRR)		1Q						

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

**February 2007**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>		<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							<b>PROJECT</b> <b>832</b>	
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	Cost to Complete	Total Cost
832 COMBAT MEDICAL MATL ED	756	3721	5275	14947	14277	5494	6217	6364		57051

**A. Mission Description and Budget Item Justification:** This project funds technical development of candidate medical products for the advancement of combat casualty care, especially far forward on the battlefield with first responders, combat lifesavers, and field medics. This primarily funds Phase 3 human clinical trials or mechanical engineering evaluations for efficacy of devices or biologics unique to military operational requirements. This work is frequently completed through a joint laboratory and contractor team with the contractor obtaining ultimate U.S. Food and Drug Administration (FDA) licensure. These products (enhanced location and diagnostic devices of patients and more potent resuscitative biologics) will decrease mortality rates and increase soldier's morale and willingness to place themselves in danger. Additionally, several products, Dental Field Treatment and Operating System (DEFTOS), Ventilatory Assist Device (VAD), and Oxygen Generator will reduce medical organizational sustainment footprint through smaller weight, cube volume, or equipment independence from supporting materiel. Priority is given to those products that provide the greatest clinical benefit balanced with the technical and financial risks.

Major contractors/intra-governmental agencies include: Bell Dental Inc., Allied Technologies Consulting, IGR Enterprises, Army Medical Department Board Test Center, Smisson-Cartledge Biomedical, SeQual Technologies, Inc., and Enginivity, Inc.

<b>Accomplishments/Planned Program:</b>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Conduct testing & milestone reviews for the following field medical treatment and treatment aid devices: (1) Dental Field Treatment & Operating System (DEFTOS): In FY06, completed long term user evaluation. Results of evaluation used to upgrade system. Test and evaluation of upgraded system were completed and results positive. In FY07, complete transition of latest model to field. (2) Ventilatory Assist Device (VAD): In FY06, continued to support the fielding process. FY07, integrate new P3I self-contained electric ventilator. In FY08, conduct technical and user acceptance testing. In FY09, conduct Milestone C. (3) Ceramic Oxygen Generator (COG): In FY08, conduct technical and user acceptance testing. In FY09, conduct Milestone C. (4) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY08, conduct user testing and evaluation of Omni II system. In FY09, conduct Milestone C review of Omni II. Initiate low rate production. (5) Battery Powered IV Fluid Warmer: In FY07, conduct airworthiness release of line-powered unit. In FY08, conduct Milestone C. (6) Cartledge Infuser (CI): In FY06, completed FDA-requested testing for 510(k) review. Initiated Low Rate Initial Production. In FY07, conduct technical/user evaluation. FY08, conduct Milestone C.	756	3619	5275	14947
Small Business Innovative Research/Small Business Technology Transfer Programs.		102		
<b>Total</b>	<b>756</b>	<b>3721</b>	<b>5275</b>	<b>14947</b>

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

**C. Acquisition Strategy** Evaluate commercially developed materiel in government-managed trials.

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

February 2007

BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

**5 - System Development and Demonstration**

**0604807A - Medical Materiel/Medical Biological Defense Equipm**

**832**

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY			PE NUMBER AND TITLE									PROJECT		
5 - System Development and Demonstration			0604807A - Medical Materiel/Medical Biological Defense Equipm									832		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Rotary Valve Pressure Swing Adsorption oxygen Generator		Sequal Technologies, Inc., San Diego, CA	1780	357		759		5275		14947			23118	
Cartledge Infuser		Smisson-Cartledge Biomedical L.L.C., Macon, GA	3110										3110	
Subtotal:			4890	357		759		5275		14947			26228	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Not Applicable														
Subtotal:														
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Not Applicable														
Subtotal:														
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater			14713	399		2962						Cont.		
Subtotal:														

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>				PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							PROJECT <b>832</b>	
than \$1M individually												
Subtotal:				14713	399		2962					Cont.

<b>Project Total Cost:</b>				<b>19603</b>	<b>756</b>		<b>3721</b>		<b>5275</b>		<b>14947</b>	<b>Cont.</b>	<b>26228</b>
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# Schedule Profile (R4 Exhibit)

February 2007

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

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipm**

PROJECT  
**832**

Event Name	FY 06				FY 07				FY 08				FY 09				FY 10				FY 11				FY 12				FY 13			
	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) Ventilatory Assist Device (MS-C)													▲ <sub>1</sub> MS C																			
(2) Ceramic Oxygen Gen Sys (MS-C)																	▲ <sub>2</sub> MS C															
(3) Rotary Valve Press Swing Oxy (MS-C)																					▲ <sub>3</sub> MS C											
(4) Battery Powered Iv Fld Warm (MS-C)																					▲ <sub>4</sub> MS C											
(5) Cartledge Infuser (MS-C)																					▲ <sub>5</sub> MS C											

# Schedule Detail (R4a Exhibit)

February 2007

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>	PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>	PROJECT <b>832</b>
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<u>Schedule Detail</u>	<u>FY 2006</u>	<u>FY 2007</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>
Ventilatory Assist Device (MS-C)				2Q				
Ceramic Oxygen Gen Sys (MS-C)				1Q				
Rotary Valve Press Swing Oxy (MS-C)				2Q				
Battery Powered Iv Fld Warm (MS-C)			4Q					
Cartledge Infuser (MS-C)			4Q					

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

**February 2007**

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>		<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							<b>PROJECT</b> <b>834</b>	
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED		2979	1856	1795	1698	1691	1789	1832		13640

**A. Mission Description and Budget Item Justification:** This project supports 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.

A major contractor is Allermed Laboratories, Inc., San Diego, CA.

<b>Accomplishments/Planned Program:</b>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
(1) Special Medical Emergency Evacuation Device (SMEED): FY06, obtained fleetwide UH-60 Air Worthiness Release for the SMEED. FY07, conduct Milestone C. (2) Life Support for Trauma and Transport (LSTAT): FY06, obtained CENTCOM CH-47 AWR for LSTAT. (3) Coliform Analyzer: In FY07, begin preliminary design of engineering development model. In FY08, finalize new design. In FY09, conduct technical testing and user evaluations.		2895	1856	1795
Small Business Innovative Research/Small Business Technology Transfer Programs		84		
<b>Total</b>		2979	1856	1795

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

**C. Acquisition Strategy** Test and evaluate in-house and commercially developed materiel in government-managed trials to meet FDA requirements.

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY			PE NUMBER AND TITLE									PROJECT		
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>									<b>834</b>		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			2317			1371		853		826			5367	
Congressional Add in Support of Chem-Bio Protection			4550										4550	
Subtotal:			6867			1371		853		826			9917	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			74			89		56		54			273	
Subtotal:			74			89		56		54			273	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			480			566		353		341			1740	
Subtotal:			480			566		353		341			1740	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater			901			953		594		574			3022	
Subtotal:			901			953		594		574			3022	

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>				PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>								PROJECT <b>834</b>	
than \$1M individually													
Subtotal:				901			953			594		574	3022

<b>Project Total Cost:</b>				<b>8322</b>			<b>2979</b>			<b>1856</b>		<b>1795</b>	<b>14952</b>
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# Schedule Profile (R4 Exhibit)

February 2007

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

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipm**

PROJECT  
**834**

Event Name	FY 06				FY 07				FY 08				FY 09				FY 10				FY 11				FY 12				FY 13			
	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) Special Medical Emergency Evacuation Device (SMEED) (MS-C)					MS C 																											

**Schedule Detail (R4a Exhibit)**

**February 2007**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>					PROJECT <b>834</b>	
<u>Schedule Detail</u>	<u>FY 2006</u>	<u>FY 2007</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>
Special Medical Emergency Evacuation Device (SMEED) (MS-C)		4Q						

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

February 2007

<b>BUDGET ACTIVITY</b> <b>5 - System Development and Demonstration</b>		<b>PE NUMBER AND TITLE</b> <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>							<b>PROJECT</b> <b>849</b>	
COST (In Thousands)	FY 2006 Actual	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	FY 2012 Estimate	FY 2013 Estimate	Cost to Complete	Total Cost
849      INFEC DIS DRUG/VACC ED	565	3139	4027	13721	13294	3830	4760	4873		48209

**A. Mission Description and Budget Item Justification:** This project funds technical development of candidate medical countermeasures for infectious diseases that occur within militarily relevant areas of the world. These products fall within three major areas: vaccines, drugs, and diagnostic kits. The funds support Phase 3 human clinical trials for large-scale efficacy testing, 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 if contracted, and speeding recovery once diagnosed. These trials are required to meet U.S. Food and Drug Administration (FDA) regulatory approval guidance, a mandatory obligation for all military products placed into the hands of medical providers or service members. 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 and production). Consequently, malaria, dysentery, hepatitis, and dengue diseases (which are found in Central Command, European Command, Southern Command, and Pacific Command areas) rise to the top of the requirement list.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Clinical trials, developmental testing, and appropriate reviews of malarial/antimalarial vaccines, drugs, and diagnostics: In FY06 completed the FDA mandated Phase 3 Malaria Rapid Diagnostic Device (MRDD) clinical trial in the United States and submitted the 510(k) Package for FDA review. In FY06, completed the enrollment phase and continued the observation and follow-up phase of the FDA-mandated Phase 1 safety trial of the Antimalarial Drug, Tafenoquine (treatment and post-exposure prophylaxis of Plasmodium vivax malaria), conducted Key Opinion Leader meetings in Brazil and Thailand, and initiated clinical site selection process for clinical field trials to bring Tafenoquine to FDA licensure. In FY07 for MRDD conduct FDAs required Cross-Reactivity Testing on spiked samples and a FDA mandated Clinical Specificity Study and submit the results to the 510(k) Package already under FDA review for approval of commercial sales; conduct a Milestone C IPR to transition MRDD to Full-Rate Production and Deployment, resulting in fielding of state-of-the-art malaria diagnostic capability for military physicians. In FY07 conduct a Design Readiness Review to re-baseline product development plan, complete the observation phase and initiate data analysis of the FDA-mandated Phase 1 safety trial, and initiate a new Phase 1 drug-drug-interaction study for Tafenoquine. In FY08, for the Tafenoquine drug, complete the Phase 1 drug-drug interactions study and perform data analysis and prepare for a Phase 3 pivotal study in Asia. In FY09, initiate a Tafenoquine Phase 3 pivotal study for a treatment indication.	441	2758	2219	6872
Prepare for conducting clinical studies, trials, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Hepatitis E Vaccine, Combined Camouflage Face Paint/Insect Repellent, a new Standard Military Insect Repellent and leishmania): In FY06, conducted a Design Readiness Review (DRR) to re-baseline Hepatitis E vaccine development based on agreement with industry partner. Conducted a DRR for the Combined Camouflage Face Paint/Insect Repellent (CCFP) in stick packaging and initiated a Soldier Acceptability Survey. In FY07, continue a technology watch on the industry partners progress with a new Hepatitis E vaccine; finalize the CCFP Soldier Acceptability Survey. In FY08, continue monitoring industry partners Hepatitis E vaccine effort; and for the CCFP complete clinical efficacy trials (laboratory and field) and their data analysis and monitor stability testing; transition a new Standard Military Insect	124	308	1808	6849

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

**February 2007**

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT		
<b>5 - System Development and Demonstration</b>	<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>	<b>849</b>		
Repellent( to replace current DEET repellent) to System Development and Demonstration (Milestone B) and initiate Phase 2b field testing; and initiate a Phase 3 pivotal trial for Topical Antileishmanial Cream. In FY09, finalize all field trial reports, complete stability testing, and conduct a Milestone C IPR to transition the CCFP to Full-Rate Production and Deployment, resulting in fielding of state-of-the-art camouflage face paint with insect repellent in stick packaging; continue Phase 2b field testing of a new Standard Military Insect Repellent; and complete the Phase 3 pivotal trial and perform data analysis for Topical Antileishmanial Cream				
Small Business Innovative Research/Small Business Technology Transfer Programs.				
Total				
	565	3139	4027	13721

**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)

February 2007

BUDGET ACTIVITY			PE NUMBER AND TITLE									PROJECT		
<b>5 - System Development and Demonstration</b>			<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>									<b>849</b>		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			7038	192		1067		1369		4665		Cont.	Cont.	Cont.
Subtotal:			7038	192		1067		1369		4665		Cont.	Cont.	Cont.
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			510	11		63		81		274		Cont.	Cont.	Cont.
Subtotal:			510	11		63		81		274		Cont.	Cont.	Cont.
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			10345	266		1475		1893		6449		Cont.	Cont.	Cont.
Subtotal:			10345	266		1475		1893		6449		Cont.	Cont.	Cont.
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			2966	96		534		684		2333		Cont.	Cont.	Cont.
Subtotal:			2966	96		534		684		2333		Cont.	Cont.	Cont.

# ARMY RDT&E COST ANALYSIS (R3)

February 2007

BUDGET ACTIVITY		PE NUMBER AND TITLE						PROJECT				
<b>5 - System Development and Demonstration</b>		<b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>						<b>849</b>				
<b>Project Total Cost:</b>		<b>20859</b>	<b>565</b>		<b>3139</b>		<b>4027</b>		<b>13721</b>	<b>Cont.</b>	<b>Cont.</b>	<b>Cont.</b>

# Schedule Profile (R4 Exhibit)

February 2007

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

PE NUMBER AND TITLE  
**0604807A - Medical Materiel/Medical Biological Defense Equipm**

PROJECT  
**849**

Event Name	FY 06				FY 07				FY 08				FY 09				FY 10				FY 11				FY 12				FY 13			
	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) Malaria Rapid Diagnostic Device (MS-C)					MS C ▲ <sub>1</sub>																											
(2) Tafenoquine Antimalarial Drug (DRR) Design Readiness Review									▲ <sub>2</sub>																							
(3) Comb Camouff Face Paint/Insect Rep (DRR) Design Readiness Review Camouff Face Paint/Insect Rep (MS-C)									▲ <sub>3</sub>								MS C ▲ <sub>4</sub>															
(5) Hepatitis E Vaccine (DRR) Design Readiness Review									▲ <sub>5</sub>																							

**Schedule Detail (R4a Exhibit)**

**February 2007**

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipm</b>						PROJECT <b>849</b>
<u>Schedule Detail</u>	<u>FY 2006</u>	<u>FY 2007</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>
Malaria Rapid Diagnostic Device (MS-C)		3Q						
Tafenoquine Antimalarial Drug (DRR)		1Q						
Comb Camoufl Face Paint/Insect Rep (DRR)		1Q						
Comb Camoufl Face Paint/Insect Rep (MS-C)				2Q				
Hepatitis E Vaccine (DRR)		1Q						