

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

February 2008

BUDGET ACTIVITY <b>5 - System Development and Demonstration</b>		PE NUMBER AND TITLE <b>0604807A - Medical Materiel/Medical Biological Defense Equipment - Eng Dev</b>								
COST (In Thousands)	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	22226	27745	34971	33613	15488	17229	17643	Continuing	Continuing	
812 MIL HIV VAC&DRUG DEV	4076	4635	4697	4541	4541	4539	4647	Continuing	Continuing	
832 COMBAT MEDICAL MATL ED	3365	5241	14852	14177	5456	6176	6325	Continuing	Continuing	
834 SOLDIER SYS PROT-ED	2917	1844	1783	1686	1679	1777	1820	Continuing	Continuing	
849 INFEC DIS DRUG/VACC ED	2852	4002	13639	13209	3812	4737	4851	Continuing	Continuing	
A11 LSTAT MEDICAL TECHNOLOGY (CA)	2130	3180							8953	
A12 BIOMEDICAL ENGINEERING TECH & ADV MATERIALS (CA)	2528								7033	
A14 CHITOSAN BANDAGE COMPONENT (CA)	4358								9628	
CS5 MED MATERIEL/MED BIO DEFENSE INITIATIVES (CA)		8843							8843	

**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 PE primarily includes conclusive 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.

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

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.

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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 2007	FY 2008	FY 2009
Previous President's Budget (FY 2008/2009)	24536	15823	35190
Current BES/President's Budget (FY 2009)	22226	27745	34971
Total Adjustments	-2310	11922	-219
Congressional Program Reductions		-178	
Congressional Rescissions			
Congressional Increases		12100	
Reprogrammings	-1637		
SBIR/STTR Transfer	-673		
Adjustments to Budget Years			-219

In FY 07 reduction of \$2.31 million was due to reprogramming to higher priorities.  
 In FY 08 increase of \$12.1 million was due to Congressional adds to the following projects:  
 A11 LSTAT Medical Technology (CA) \$3.2 million  
 CS5 Medical Materiel/Med Bio Defense Initiatives \$8.9 million.

In FY 09 decrease of \$219 thousand was due to adjustments to Budget Years.

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

**February 2008**

<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 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	4076	4635	4697	4541	4541	4539	4647	Continuing	Continuing

**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><u>Accomplishments/Planned Program:</u></b>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Reviews, evaluations and trials of Human Immunodeficiency Virus (HIV) Vaccine: In FY07, continued the observation and follow-up phase of the multi-year Phase 3 trial of the Prime-Boost HIV Vaccine in Thailand, conducted and Interim Analysis of study data to date, and conducted 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 for the HIV Vaccine.	4076	4505	4697
Small Business Innovative Research/Small Business Technology Transfer Programs.		130	
<b>Total</b>	<b>4076</b>	<b>4635</b>	<b>4697</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)

February 2008

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 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	9721	2768		3282		3326			19097	
Subtotal:			9721	2768		3282		3326			19097	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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			310	45		46		47			448	
Subtotal:			310	45		46		47			448	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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	2755	1173		1213		1229			6370	
Subtotal:			2755	1173		1213		1229			6370	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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

# ARMY RDT&E COST ANALYSIS (R3)

February 2008

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			314	90		94		95		593
Subtotal:			314	90		94		95		593
<b>Project Total Cost:</b>			<b>13100</b>	<b>4076</b>		<b>4635</b>		<b>4697</b>		<b>26508</b>

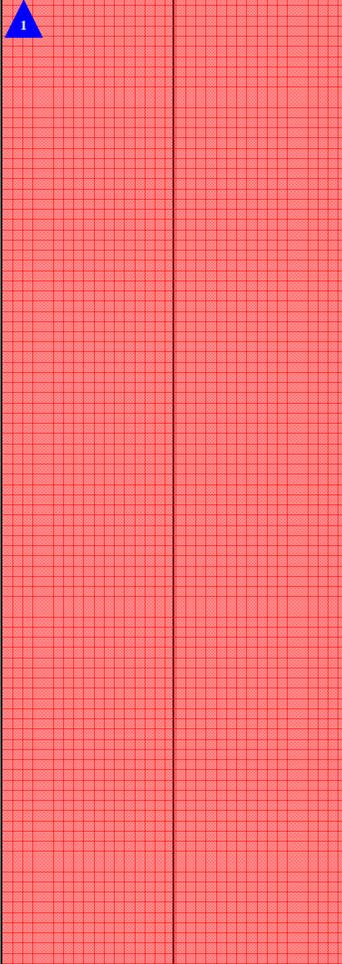
# Schedule Profile (R4 Exhibit)

February 2008

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 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) HIV Vaccine Design Readiness Review (DRR)																												



**Schedule Detail (R4a Exhibit)**

**February 2008**

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 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 2008**

<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 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	3365	5241	14852	14177	5456	6176	6325	Continuing	Continuing

**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 and cube volume, or equipment independence from supporting materiel. Priority is given to those products that provide the greatest clinical benefit balance 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, SeQual Technologies, Inc., and Enginivity, Inc.

<b>Accomplishments/Planned Program:</b>	<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 FY07, completed transition of latest model to field. (2) Ceramic Oxygen Generator (COG): In FY08, complete development of new prototype to satisfy form and fit requirements. In FY09, conduct technical and user evaluations. Obtain FDA clearance. Milestone C. (3) 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. (4) Battery Powered IV Fluid Warmer: In FY07, conducted airworthiness release of line-powered unit. In FY08, conduct Milestone C.	3365	5097	14852
Small Business Innovative Research/Small Business Technology Transfer Programs.		144	
<b>Total</b>	<b>3365</b>	<b>5241</b>	<b>14852</b>

**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)

February 2008

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 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	2137	703		5241		14852			22933	
Cartledge Infuser		Smisson-Cartledge Biomedical L.L.C., Macon, GA	3110								3110	
Subtotal:			5247	703		5241		14852			26043	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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 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 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

# ARMY RDT&E COST ANALYSIS (R3)

February 2008

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>832</b>		
No product/contract costs greater than \$1M individually			15112	2662					Cont.	Cont.	
Subtotal:			15112	2662					Cont.	Cont.	
<b>Project Total Cost:</b>											
			<b>20359</b>	<b>3365</b>		<b>5241</b>		<b>14852</b>		<b>Cont.</b>	<b>Cont.</b>

# Schedule Profile (R4 Exhibit)

February 2008

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 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) Ceramic Oxygen Gen Sys (MS-C)									▲ <sub>1</sub> MS C																			
(2) Rotary Valve Press Swing Oxy (MS-C)													▲ <sub>2</sub> MS C															
(3) Battery Powered Iv Fld Warm (MS-C)													▲ <sub>3</sub> MS C															



**Schedule Detail (R4a Exhibit)**

**February 2008**

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>832</b>
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<u>Schedule Detail</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 2008**

<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 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	2917	1844	1783	1686	1679	1777	1820	Continuing	Continuing

**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.

Major contractor is Allermed Laboratories, Inc., San Diego, CA.

<b><u>Accomplishments/Planned Program:</u></b>	<b><u>FY 2007</u></b>	<b><u>FY 2008</u></b>	<b><u>FY 2009</u></b>
(1) Special Medical emergency Evacuation Device (SMEED): FY 08, conduct Milestone C. (2) Life Support for Trauma and Transport (LSTAT): In FY08, conduct AWR for LSTAT-Lite in preparation for LRIP. (3) Coliform analyzer: In FY08, finalize design. In Fy 09, conduct technical testing and user evaluation.	2917	1792	1783
Small Business Innovative Research/Small Business Technology Transfer Programs		52	
<b>Total</b>	<b>2917</b>	<b>1844</b>	<b>1783</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)

February 2008

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 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 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 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 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

# ARMY RDT&E COST ANALYSIS (R3)

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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			901	891		582		562		2936	
Subtotal:			901	891		582		562		2936	
<b>Project Total Cost:</b>			<b>8322</b>	<b>2917</b>		<b>1844</b>		<b>1783</b>		<b>14866</b>	

# Schedule Profile (R4 Exhibit)

February 2008

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 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) Special Medical emergency Evacuation Device (SMEED) (MS-C)	MS C 																											



**Schedule Detail (R4a Exhibit)**

**February 2008**

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 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							

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<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 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 INFECDIS DRUG/VACC ED	2852	4002	13639	13209	3812	4737	4851	Continuing	Continuing

**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/devices. The funds support 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 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). Currently malaria, dysentery, hepatitis, and dengue diseases (which are found in Central Command, European Command, Southern Command, and Pacific Command areas) are at the top of the infectious disease requirements list.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Clinical trials, developmental testing, & reviews of malarial/antimalarial vaccines, drugs, diagnostics and insect repellents: In FY07 for Malaria Rapid Diagnostic Device (MRDD) conducted FDA's required Cross-Reactivity Laboratory Testing on human blood samples spiked with levels of infectious bacteria, parasites, and viruses to characterize if the MRDD cross-reacts with non-malaria infectious agents, conducted a FDA mandated Human Clinical Specificity Trial with volunteers who had a fever or history of fever and live within the United States in an area with low incidence of malaria. and submitted both test results to the FDA for their review, obtained FDA Clearance (approval) for commercial sales by the manufacturer, and developed an External Control Kit (to accompany the actual MRDD device) for use by clinical laboratories in support of their good laboratory practices. In FY07 for anti-malarial drug, Tafenoquine, conducted a Design Readiness Review to re-baseline product development plan and began protocol review for a drug-drug-Interaction human clinical trial; In FY07 for the Combined Camouflage Face Paint/Insect Repellent (CCFP) obtained approval for commercial sales from the Environmental Protection Agency (EPA) and prepared a clinical protocol for a soldier acceptability clinical trial. In FY08 for the MRDD program obtain FDA approval of the External Control Kit for marketing with the MRDD, and conduct a Milestone C. In FY08, for Tafenoquine ,begin a drug-drug interaction human clinical trial and begin pre-trial planning for a efficacy and safety human clinical trial in a malaria endemic country; and conduct the CCFP soldier acceptability clinical trial. In FY09, for Tafenoquine complete the drug-drug interaction clinical trial and conduct data analysis, continue pre-trial activities for Tafenoquine large-scale efficacy and safety human clinical trial (treatment indication) in a malaria endemic country; and for CCFP provide assistance to DLA.	2471	2100	6790
Clinical trials, developmental testing, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis, Dengue, and other viral diseases): In FY07, for the Paromomycin/Gentamicin Topical Antileishmanial Cream (for treatment of cutaneous (skin) leishmaniasis), conducted laboratory assay validations, manufactured drug batches for clinical use, continued stability testing of drug lots, and conducted pre-trial regulatory coordination for the pivotal human efficacy clinical trial in Tunisia; continued a technology watch on	381	1808	6849

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**February 2008**

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>	
the industry partner's progress with a new Hepatitis E vaccine; and for Dengue Tetravalent Vaccine (DTV) conducted potency and stability testing of manufactured vaccine lots. In FY08, continue monitoring industry partner's Hepatitis E vaccine effort; for the DTV continue vaccine potency & stability testing and support pre-trial activities in Thailand for an expanded safety and efficacy human clinical trial; and for the Topical Antileishmanial Cream begin preparing the FDA licensure submission package and continue stability testing of drug lots. In FY09 for Topical Antileishmanial Cream continue developing the FDA licensure submission package and continue the Tunisia pivotal human clinical efficacy trial; and for the DTV vaccine begin in Thailand the expanded safety and efficacy human clinical trial and continue vaccine potency & stability testing.			
Small Business Innovative Research/Small Business Technology Transfer Programs.		94	
<b>Total</b>	<b>2852</b>	<b>4002</b>	<b>13639</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)

February 2008

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 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			7230	967		1369		4665		Cont.	Cont.	Cont.
Subtotal:			7230	967		1369		4665		Cont.	Cont.	Cont.
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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			521	63		81		274		Cont.	Cont.	Cont.
Subtotal:			521	63		81		274		Cont.	Cont.	Cont.
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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			10611	1388		1893		6449		Cont.	Cont.	Cont.
Subtotal:			10611	1388		1893		6449		Cont.	Cont.	Cont.
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	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			3062	434		659		2251		Cont.	Cont.	Cont.
Subtotal:			3062	434		659		2251		Cont.	Cont.	Cont.

# ARMY RDT&E COST ANALYSIS (R3)

February 2008

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:	3062	434		659		2251	Cont.	Cont.	Cont.

<b>Project Total Cost:</b>	<b>21424</b>	<b>2852</b>		<b>4002</b>		<b>13639</b>	<b>Cont.</b>	<b>Cont.</b>	<b>Cont.</b>
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# Schedule Profile (R4 Exhibit)

February 2008

**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 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) Malaria Rapid Diagnostic Device (MS-C)	MS C ▲ <sub>1</sub>																											
(2) Tafenoquine Antimalarial Drug (DRR) Design Readiness Review	▲ <sub>2</sub>																											
(3) Comb Camoufl Face Paint/Insect Rep Design Readiness Review	▲ <sub>3</sub>																											
(4) Comb Camoufl Face Paint/Insect Rep (MS-C)									MS C ▲ <sub>4</sub>																			
(5) Hepatitis E Vaccine (DRR) Design Readiness Review	▲ <sub>5</sub>																											
(6) New Military Insect Repellent (MS-B)									MSB ▲ <sub>6</sub>																			



**Schedule Detail (R4a Exhibit)**

**February 2008**

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 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	1Q						
New R4 Event							
Comb Camoufl Face Paint/Insect Rep (MS-C)			2Q				
Hepatitis E Vaccine (DRR)	1Q						
New Military Insect Repellent (MS-B)			2Q				