

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2004

BUDGET ACTIVITY

5 - System Development and Demonstration

PE NUMBER AND TITLE

0604807A - Medical Materiel/Medical Biological Defense Equipm

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	18769	22615	11727	12402	14322	15540	15567	Continuing	Continuing
812 MIL HIV VAC&DRUG DEV	0	3211	3723	4169	4463	4468	4464	Continuing	Continuing
832 COMBAT MEDICAL MATL ED	9381	5666	3443	3818	3732	5227	5251	Continuing	Continuing
834 SOLDIER SYS PROT-ED	768	5900	1055	874	2978	1801	1748	Continuing	Continuing
849 INFEC DIS DRUG/VACC ED	3269	3780	3506	3541	3149	4044	4104	Continuing	Continuing
A10 RAMAN CHEMICAL BIOTHRREAT DETECTION PROGRAM	5351	0	0	0	0	0	0	0	5353
A11 LSTAT MEDICAL TECHNOLOGY (CA)	0	2078	0	0	0	0	0	0	2078
A12 BIOMEDICAL ENGINEERING TECH & ADV MATERIALS (CA)	0	990	0	0	0	0	0	0	990
A13 PRESSURE SWING ABSORPTION OXYGEN CONCENTRATOR (CA)	0	990	0	0	0	0	0	0	990

A. Mission Description and Budget Item Justification: This program element (PE) funds advanced development of medical materiel within system demonstration and low rate initial production portions of the acquisition life cycle. The PE supports products that successfully transitioned through the Systems Development and Demonstration In-Process Review (IPR). This principally includes Phase 3 human clinical trials as well as related stability and production manufacturing testing for medical pharmaceuticals, biologics, and devices. Further operational testing (OT&E) for military unique requirements is evaluated and fulfilled.

Infectious disease vaccines and preventive drugs that will reduce the risk of service members contracting debilitating or fatal diseases, especially within a battlefield of growing potentials as urban warfare risks increase. Disease and non-battle injuries are the largest contributor to medical footprint. Significant reductions in echelon 3 facilities can be achieved by reducing the number of ill soldiers. Equally important, the reduction of patient evacuation within Future Force (F2) units will act as a force multiplier because timely replacement of these uniquely skilled soldiers will be nearly impossible.

Combat Casualty Care devices and biologics that have two major focuses: enhance forward care at the first responder level and reduce footprint of medical organizations for greater mobility and easier sustainment. The F2 concept will place soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). This requires greater capability in the hands of medics and first responders to save lives and extend stabilization. Reduction in weight, cube, and sustainment will allow medical units to increase mobility and maintain contact with its supported

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maneuver units.

Soldier Performance Enhancers in the form of drugs or diagnostics that will allow commanders to increase soldiers' cognitive awareness and stamina. This has direct relationship to increased soldier capabilities and a potential to reduce casualties.

This program is managed by the U.S. Army Medical Research and Materiel Command.

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

This program supports the Future Force transition path of the Army Transformation Campaign Plan (TCP).

Major contractors/intragovernmental agencies include Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, SeQual Technologies, Inc., and the American National Red Cross.

<u>B. Program Change Summary</u>	FY 2003	FY 2004	FY 2005
Previous President's Budget (FY 2004)	18790	12202	11715
Current Budget (FY 2005 PB)	18769	22615	11727
Total Adjustments	-21	10413	12
Congressional program reductions		-214	
Congressional rescissions			
Congressional increases		10650	
Reprogrammings	-21	-23	
SBIR/STTR Transfer			
Adjustments to Budget Years			12

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

PROJECT

812

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
812 MIL HIV VAC&DRUG DEV	0	3211	3723	4169	4463	4468	4464	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 sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials. 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. This program supports the Future Force transition path of the Army Transformation Campaign Plan (TCP).

<u>Accomplishments/Planned Program</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
In FY03, program transferred to National Institutes of Health (NIH), and funding was provided to the U.S. Army Medical Research and Materiel Command (MRMC) to continue efforts on this vaccine; continued protocol development and approval for a Phase 3 field efficacy trial of a prime-boost vaccine strategy. In FY04, program returns to the Army. Begin multi-year Phase 3 clinical trial in Thailand to determine effectiveness of prime-boost HIV vaccine against the clade E virus strain. In FY05, continue multi-year Phase 3 clinical trial to determine effectiveness of prime boost HIV vaccine against the clade E virus strain.	0	3118	3723
Small Business Innovative Research/Small Business Technology Transfer Programs	0	93	0
Totals	0	3211	3723

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 2004			
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 812		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	2200	0		2182		2634		0	7016	0
Subtotal:			2200	0		2182		2634		0	7016	0
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			201	0		32		38		0	271	0
Subtotal:			201	0		32		38		0	271	0

ARMY RDT&E COST ANALYSIS(R3)									February 2004			
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 812		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Test and Evaluation	Government Laboratory	Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD	0	0		844		976		0	1820	0
Subtotal:			0	0		844		976		0	1820	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			105	0		153		75		0	333	0
Subtotal:			105	0		153		75		0	333	0
Project Total Cost:			2506	0		3211		3723		0	9440	0

Schedule Profile (R4 Exhibit)	February 2004
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February 2004


BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm
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PROJECT
812

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

812

Event Name	FY 02				FY 03				FY 04				FY 05				FY 06				FY 07				FY 08				FY 09			
	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) MS C																					HIV Vaccine 											

Schedule Detail (R4a Exhibit)						February 2004				
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm		PROJECT 812				
<u>Schedule Detail</u>				FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
HIV Vaccine (MS C)								4Q		

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

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PE NUMBER AND TITLE

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

PROJECT

832

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
832 COMBAT MEDICAL MATL ED	9381	5666	3443	3818	3732	5227	5251	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 life savers, 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 assuming ultimate U.S. Food and Drug Administration (FDA) licensure. These products (enhanced location and diagnostic devices of patients; more potent resuscitative biologics) will decrease mortality rates, thereby increasing soldier morale and willingness to place themselves in danger. Additionally, several products (Dental Field Treatment and Operating System (DEFTOS), Ventilated Assist Device, Non-Contact Respiration Monitor, One-Handed Tourniquet, Oxygen Generator, Cartilage Infuser, Hemostatic Dressing, and Blood Processor) will reduce medical organizational sustainment footprint through smaller weight and cube or equipment independence from supporting materials. Priority is given to those products that provide the greatest clinical benefit balanced with the technical and financial risks. These products support both the Army Transformation Campaign Plan (TCP) and Future Force doctrine/organizational structure.

Major contractors/intragovernmental agencies include: Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, Mission Medical Inc., Smission-Cartilage Biomedical, Nexus Medical LLC, Sequal Technologies, Inc, Naval Air Warfare Center Weapons Division, and the American National Red Cross.

Accomplishments/Planned Program

Hemostatic Dressing (HD): FY03: Completed Battlefield Investigational New Drug Protocol, received FDA approval, and implemented protocol in Operation Iraqi Freedom. Delayed Phase 1/2 clinical trials due to American Red Cross financial problems (delay continues, expected resolution FY04). FY04: Directly compare HD to a competitor, the Chitosan Bandage, in a series of animal studies. FY05: Continuation of this program is dependent on the outcome of the comparative studies.

FY 2003 FY 2004 FY 2005

6150 300 1790

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Defense Equipm**

PROJECT

832

Accomplishments/Planned Program (continued)

Conduct testing and milestone IPRs for field medical treatment and treatment aid devices. (1) Dental Field Treatment and Operating System (DEFTOS): FY03: Completed technical, user, and environmental testing; designed new prototypes implementing recommended changes from user evaluation. Built, received, and re-evaluated the new prototypes. FY04: Attain Milestone C. (2) Thawed Blood Processing System (TBPS): FY03: Obtained clinical trials data from FDA. Prepared for technical and user evaluations of alternative system, FDA testing and regulatory submission. FY04: Submit for FDA clearance. Complete Milestone C. (3) Ceramic Oxygen Generator System (COGS): FY03: Completed fabrication of ceramic oxygen cell structures. Built and demonstrated a 3-liter per minute prototype generator. Began developing heat exchangers, enclosure, controls, and start up heater. FY04: Start development of full-scale engineering development model. FY05: Continue development of full-scale model, and refine manufacturing process to use existing device manufacturing techniques found in the electronics industry. (4) Ventilatory Assist Device (VAD). FY03: Completed user evaluation, prepared final test report. FY04: Develop an FDA approved anesthetic agent scrubber that will not require exterior venting, conduct clinical use and evaluation of the completed anesthesia system. (5) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): FY05: Conduct user evaluation and attain Milestone C. (6) Cartilage Infuser: FY03: Conducted human factors assessment; selected subcontractor for circuit board design. FY04: continue product development. (7) Hypertonic Saline Dextran (HSD): FY03: Reinitiated the development of HSD and developed a clinical trial plan. FY04: Receive FDA approval for the clinical development plan. Conduct scientific and human subject research reviews of the Phase 3 clinical trial protocol for prehospital treatment of trauma patients.

FY 2003

3231

FY 2004

5204

FY 2005

1653

Small Business Innovative Research/Small Business Technology Transfer Programs

0

162

0

Totals

9381

5666

3443

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

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

ARMY RDT&E COST ANALYSIS(R3)									February 2004			
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 832		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Hemostatic Dressing		American National Red Cross, Charlotte, NC	12150	6150		300		964		Continue	19564	0
b . Thawed Blood Processing System		Mission Medical Inc. , Fremont, CA	1625	1000		1029		0		Continue	3654	0
c . Rotary Valve Pressure Swing Adsorption oxygen Generator		Sequal Technologies, Inc., San Diego, CA	0	0		1120		1437		0	2557	0
d . Cartledge Infuser		Smisson-Cartledge Biomedical L.L.C., Macon, GA	0	1200		1940		0		0	3140	0
Subtotal:			13775	8350		4389		2401		Continue	28915	0

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BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT		
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					832		
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . Not Applicable			0	0		0		0		0	0	0
Subtotal:			0	0		0		0		0	0	0

ARMY RDT&E COST ANALYSIS(R3)									February 2004			
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT		
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					832		
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			7609	1031		1277		1042		Continue	10959	0
Subtotal:			7609	1031		1277		1042		Continue	10959	0
Project Total Cost:			21384	9381		5666		3443		Continue	39874	0

Schedule Profile (R4 Exhibit)	February 2004
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February 2004

BUDGET ACTIVITY
5 - System Development and Demonstration

PE NUMBER AND TITLE	PROJECT
0604807A - Medical Materiel/Medical Biological Defense Equipm	832

832

[illegible]

Schedule Detail (R4a Exhibit)						February 2004	
BUDGET ACTIVITY 5 - System Development and Demonstration			PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm			PROJECT 832	
<u>Schedule Detail</u>	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
Hemostatic Dressing (MS B); (MS C)		4Q		4Q			
Dental Field Treatment and Operating System (MS C)		4Q					
Thawed Blood Processing System (MS C)		4Q					
Ceramic Oxygen Generator Systems (MS B); (MS C)		3Q		4Q			
Rotary Valve Pressure Swing Oxygen		3Q					
Ventilatory Assist Device (MS C)		3Q					

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PE NUMBER AND TITLE

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

PROJECT

834

COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED	768	5900	1055	874	2978	1801	1748	Continuing	Continuing

A. Mission Description and Budget Item Justification: This project supports system development and demonstration of preventive medicine materiel, including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions. Focus is on reduction in the incidence 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 Allarmed Laboratories, Inc., San Diego, CA. This program supports the Future Force transition path of the Army Transformation Campaign Plan (TCP).

Accomplishments/Planned Program	FY 2003	FY 2004	FY 2005
In FY03, produced the U.S. Food and Drug Administration (FDA)-required three-lot consistency lots of the Leishmania tropica skin test and initiated planning and contract modification to conduct a Phase 1 safety trial. In FY04, complete production and Phase I safety trial of Leishmania skin test. In FY05, fund the Air Worthiness Certification of the Special Medical Emergency Evacuation Device (SMEED), Life Support for Trauma and Transport (LSTAT) Next Generation, and the Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG).	768	1179	1055
Congressional Adds in support of Chem-Bio Protection	0	4550	0
Small Business Innovative Research/Small Business Technology Transfer Programs	0	171	0
Totals	768	5900	1055

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

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

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)		February 2004
BUDGET ACTIVITY 5 - System Development and Demonstration	PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm	PROJECT 834
<p>meet FDA requirements.</p>		

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BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT		
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					834		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			672	612		737		714		0	2735	0
b . Congressional Add in Support of Chem-Bio Protection			0	0		4550		0		0	4550	0
Subtotal:			672	612		5287		714		0	7285	0
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			0	0		42		32		0	74	0
Subtotal:			0	0		42		32		0	74	0

ARMY RDT&E COST ANALYSIS(R3)									February 2004				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					834			
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			0	0		127		96		0	223	0	
Subtotal:			0	0		127		96		0	223	0	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			179	156		444		213		0	992	0	
Subtotal:			179	156		444		213		0	992	0	
Project Total Cost:			851	768		5900		1055		0	8574	0	

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							February 2004		
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm				PROJECT 849	
COST (In Thousands)	FY 2003 Actual	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
849 INFEC DIS DRUG/VACC ED	3269	3780	3506	3541	3149	4044	4104	Continuing	Continuing
<p>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 and civilian contracted pharmaceutical firms, 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: the extent of the disease within the Combatant Commands theater of operations, the clinical severity of the disease, the technical maturity of the proposed solution, and the affordability of the solution (development and production). Consequently, malaria, dysentery, hepatitis, and dengue diseases (which are found in CENTCOM, EUCOM, SOUTHCOM, and PACOM areas) come to the top of the requirement. The reduction in risk to contract infectious diseases within the force supports the Army Transformation Campaign Plan (TCP) and directly enables the Future Force concept through reduction of evacuations of uniquely qualified soldiers and decrease in medical footprint to sustain the evacuees.</p>									

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BUDGET ACTIVITY 5 - System Development and Demonstration		PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm		PROJECT 849
<u>Accomplishments/Planned Program</u>		FY 2003	FY 2004	FY 2005
Clinical trials, developmental testing, and appropriate reviews of malarial/antimalarial vaccines, drugs, and diagnostics: In FY03, completed a contract modification to conduct true negative trials and initiated the fingerstick (OCONUS) trial with the Malaria Rapid Diagnostic Device (MRDD); initiated a Phase 1 safety study (mandated by the FDA) on the antimalarial drug tafenoquine; began site preparation for two, pivotal Phase 3 field efficacy trials of tafenoquine. In FY04, continue the Phase 1 study of tafenoquine with the addition of a second site; continue OCONUS site preparation for tafenoquine Phase 3 trials (2 sites); conduct true negative trial and complete the fingerstick (OCONUS) study of the MRDD. In FY05, initiate two Phase 3 studies (Kenya and Indonesia planned) to evaluate effectiveness of tafenoquine; conduct a MS C IPR to transition the MRDD to full-rate production and deployment; conduct a clinical design review for the RTS,S/improved adjuvant (P. falciparum) malaria vaccine.		2512	1354	195
Studies, trials, and reviews of diarrheal vaccines. In FY03, completed all data analyses for all efficacy trials of the Enterotoxigenic Escherichia coli (ETEC) vaccine for the prevention of traveler's diarrhea; initiated a Special IPR to terminate development of the current ETEC candidate vaccine; review indicated the current vaccine was not efficacious.		647	989	1124
Clinical studies and trials, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis, Paromomycin, Tick-borne Encephalitis Vaccine (TBEV), and Hepatitis E). In FY03, initiated a Phase 2 efficacy trial to determine the effectiveness of paromomycin/gentamicin topical antileishmanial; produced 3 FDA required consistency lots of the Leishmania tropica skin test and initiated planning and contract modification to conduct a Phase 1 clinical study. In FY04, initiate non-clinical testing of the new camouflage face paint formulation to meet Environmental Protection Agency requirements. In FY05, complete non-clinical testing of new camouflage face paint formulations and initiate planning for a Phase 1 safety study.		110	1360	1699
In FY05, initiate a Phase 3 efficacy trial of the dengue tetravalent vaccine in a dengue endemic area OCONUS.		0	0	488
Small Business Innovative Research/Small Business Technology Transfer Programs		0	77	0
Totals		3269	3780	3506

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<p><u>B. Other Program Funding Summary:</u> Not applicable for this item.</p> <p><u>C. Acquisition Strategy:</u> Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.</p>		

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BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					849			
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			3526	1112		1220		1168		Continue	7026	Continue	
Subtotal:			3526	1112		1220		1168		Continue	7026	Continue	
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			299	65		76		67		Continue	507	Continue	
Subtotal:			299	65		76		67		Continue	507	Continue	

ARMY RDT&E COST ANALYSIS(R3)									February 2004				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					0604807A - Medical Materiel/Medical Biological Defense Equipm					849			
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			5521	1537		1835		1695		Continue	10588	Continue	
Subtotal:			5521	1537		1835		1695		Continue	10588	Continue	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2003 Cost	FY 2003 Award Date	FY 2004 Cost	FY 2004 Award Date	FY 2005 Cost	FY 2005 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			1207	555		649		576		Continue	2987	Continue	
Subtotal:			1207	555		649		576		Continue	2987	Continue	
Project Total Cost:			10553	3269		3780		3506		Continue	21108	Continue	

Schedule Profile (R4 Exhibit)																				February 2004													
BUDGET ACTIVITY 5 - System Development and Demonstration										PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm														PROJECT 849									
Event Name		FY 02				FY 03				FY 04				FY 05				FY 06				FY 07				FY 08				FY 09			
		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) Project Terminated						ETEC Vaccine				1																							
(2) MS C						Tafenoquine Antimalarial Drug				2																							
(3) MS C						Malaria Rapid Diagnostic Device				3																							
(4) Transition to Commercial Partner						Paromomycin/Gentamicin				4																							
(5) CDR						RTS,S Malaria Vaccine				5																							
(6) CDR						Dengue Tetravalent Vaccine				6																							

Schedule Detail (R4a Exhibit)						February 2004	
BUDGET ACTIVITY 5 - System Development and Demonstration			PE NUMBER AND TITLE 0604807A - Medical Materiel/Medical Biological Defense Equipm			PROJECT 849	
<u>Schedule Detail</u>	FY 2003	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009
ETEC vaccine (Terminated)		1Q					
Tafenoquine antimalarial drug (MS C)				3Q			
Malaria Rapid Diagnostic Device (MS C)			3Q				
Paromomycin/Gentamicin (Transition to Commercial Developer)		3-4Q					
RTS,S/improved adjuvant (P. falciparum) malaria vaccine (Critical Design Review)			1Q				
Dengue tetravalent vaccine (Critical Design Review)			3Q				