

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

February 2005

BUDGET ACTIVITY

5 - System Development and Demonstration

PE NUMBER AND TITLE

0604□0□A - Medical Materiel/Medical Biological Defense Equipm

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	21820	19325	5627	14418	16017	35984	35204	16112	0	176341
812 MIL HIV VAC&DRUG DEV	3098	3567	4201	4541	4681	4707	4544	4542	0	33881
832 COMBAT MEDICAL MATL ED	5467	4260	824	3714	5386	15374	14984	5800	0	65190
834 SOLDIER SYS PROT-ED	5693	1011	0	3030	1887	1844	1780	1778	0	17791
849 INFEC DIS DRUG/VACC ED	3647	3392	602	3133	4063	14059	13896	3992	0	50053
A11 LSTAT MEDICAL TECHNOLOGY (CA)	2005	1727	0	0	0	0	0	0	0	2078
A12 BIOMEDICAL ENGINEERING TECH & ADV MATERIALS (CA)	955	0	0	0	0	0	0	0	0	990
A13 PRESSURE SWING ABSORPTION OXYGEN CONCENTRATOR (CA)	955	0	0	0	0	0	0	0	0	990
A14 CHITOSAN BANDAGE COMPONENT (CA)	0	2013	0	0	0	0	0	0	0	2013
A15 BIOTERRORISM EDUCATION (CA)	0	958	0	0	0	0	0	0	0	958
A16 CHEMICAL-BIOLOGICAL CASUALTY TREATMENT (CA)	0	2397	0	0	0	0	0	0	0	2397

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 (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. More importantly, 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.

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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.

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

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

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<u>B. Program Change Summary</u>	FY 2005	FY 2006	FY 2007
Previous President's Budget (FY 2005)	11727	12402	14322
Current Budget (FY 2006/2007 PB)	19325	5627	14418
Total Adjustments	7598	-6775	96
Net of Program/Database Changes			
Congressional Program Reductions	-283		
Congressional Rescissions			
Congressional Increases	8400		
Reprogrammings			
SBIR/STTR Transfer	-519		
Adjustments to Budget Years		-6775	96

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5 - System Development and Demonstration

PE NUMBER AND TITLE

**0604□0□A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

□12

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
812 MIL HIV VAC&DRUG DEV	3098	3567	4201	4541	4681	4707	4544	4542	0	33881

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.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
In FY04, initiated a multi-year Phase 3 clinical trail in Thailand to determine the effectiveness of a prime-boost strategy (HIV Vaccine (HIVV)) of vaccination against the clade E virus strain of HIV. In FY05, FY06, FY07, continue the extensive Phase 3 field trial of the HIVV in Thailand. MS C decision expected to be in FY 07.	3008	3567	4201	4541
Small Business Innovative Research/Small Business Technology Transfer Programs	90	0	0	0
Totals	3098	3567	4201	4541

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 2005				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					0604□0□A - Medical Materiel/Medical Biological Defense Equipm					□12			
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	4400	2532		2983		3223		0	13138	0	
Subtotal:			4400	2532		2983		3223		0	13138	0	
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			233	38		42		45		0	358	0	
Subtotal:			233	38		42		45		0	358	0	

ARMY RDT&E COST ANALYSIS(R3)									February 2005			
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 0604□0□A - Medical Materiel/Medical Biological Defense Equipm					PROJECT □12		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 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	806	927		1092		1180		0	4005	0
Subtotal:			806	927		1092		1180		0	4005	0
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			165	70		84		93		0	412	0
Subtotal:			165	70		84		93		0	412	0
Project Total Cost:			5604	3567		4201		4541		0	17913	0

Schedule Profile (R4 Exhibit)	
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February 2005

BUDGET ACTIVITY

PE NUMBER AND TITLE

PROJECT

5 - System Development and Demonstration

060400A - Medical Materiel/Medical Biological

12

Event Name	FY 04				FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11			
	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																			
1																																

Schedule Detail (R4a Exhibit)							February 2005	
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604□0□A - Medical Materiel/Medical Biological Defense Equipm				PROJECT □12

<u>Schedule Detail</u>	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
HIV Vaccine (MS C)				4Q				

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

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BUDGET ACTIVITY

5 - System Development and Demonstration

PE NUMBER AND TITLE

**0604 0 A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

32

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
832 COMBAT MEDICAL MATL ED	5467	4260	824	3714	5386	15374	14984	5800	0	65190

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 soldiers' 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, Cartledge Infuser, Hemostatic Dressing, and Thawed Blood Processing System) 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.

Major contractors/intra-governmental agencies include: Cambridge Consultants Corporation, IGR Enterprises, Army Medical Department Board Test Center, Smission-Cartledge Biomedical, and SeQual Technologies, Inc.

Accomplishments/Planned Program

Hemostatic Dressing (HD): In FY04, closed out contract with American Red Cross (ARC) due to ARC financial problems and subsequent program unaffordability. Procured HDs for additional laboratory testing. In FY05, perform analysis of alternative Fibrin technologies.

FY 2004	FY 2005	FY 2006	FY 2007
430	1051	0	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2a Exhibit)

February 2005

BUDGET ACTIVITY

5 - System Development and Demonstration

PE NUMBER AND TITLE

**0604 0 A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

32

Accomplishments/Planned Program (continued)

Conduct testing & milestone reviews for the following field medical treatment and treatment aid devices: (1) Dental Field Treatment & Operating System (DEFTOS): In FY04, continued user evaluation and conducted Milestone C. Placed procurement order for 131 systems. In FY05, field systems to high priority units.
(2) Thawed Blood Processing System (TBPS): In FY04, reassessed Mission Medical Inc. program viability considering Haemonetics Corporation's progress and congressional interest. Initiated comparison testing and evaluation of two competing systems. In FY05, complete testing and evaluation. In FY06, conduct Milestone C In-Progress Review.
(3) Ceramic Oxygen Generator (COG): In FY04, developed low power consumption Oxygen Generator cells and designed portable oxygen generators. In FY05, conduct milestone A review and fabricate first portable Oxygen Generator prototype. In FY06, conduct user and technical testing and conduct milestone B review. In FY07, develop the engineering pre-production prototype and obtain FDA clearance.
(4) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY04, design feed air compressor and develop prototype lightweight portable oxygen generator. In FY05, reduce oxygen generator weight and size and conduct milestone B in-progress review. In FY06, develop engineering pre-production prototype and conduct technical and user testing and evaluation as well as conduct milestone C in-progress review. In FY07, initiate low rate production.
(5) Ventilatory Assist Device (VAD): In FY04, integrated ventilator drive unit with the anesthesia vaporizer. Produced user-training materials. In FY05, conduct technical and user testing, make any required modifications, and hold milestone C in-progress review. (6) Cartledge Infuser (CI): In FY04, developed initial prototype system. In FY05, conduct technical/user testing, finalize design, develop automated manufacturing process, and obtain FDA clearance of infuser system an

FY 2004

4881

FY 2005

3209

FY 2006

824

FY 2007

3714

Small Business Innovative Research/Small Business Technology Transfer Programs

156

0

0

0

Totals

5467

4260

824

3714

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 2005				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					060400A - Medical Materiel/Medical Biological Defense Equipm					32			
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . Rotary Valve Pressure Swing Adsorption oxygen Generator		Sequal Technologies, Inc., San Diego, CA	482	1778		0		0		0	2260	0	
b . Cartledge Infuser		Smisson-Cartledge Biomedical L.L.C., Macon, GA	3110	0		0		0		0	3110	0	
Subtotal:			3592	1778		0		0		0	5370	0	
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 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 2005				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					060400A - Medical Materiel/Medical Biological Defense Equipm					32			
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 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	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			11753	2482		824		3714		Continue	18773	0	
Subtotal:			11753	2482		824		3714		Continue	18773	0	
Project Total Cost:			15345	4260		824		3714		Continue	24143	0	

Schedule Profile (R4 Exhibit)																							February 2005										
BUDGET ACTIVITY 5 - System Development and Demonstration												PE NUMBER AND TITLE 060400A - Medical Materiel/Medical Biological Defense Equipm																		PROJECT 32			
Event Name		FY 04				FY 05				FY 06				FY 07				FY 08				FY 09				FY 10				FY 11			
		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) FRP&D	Dental Field Operating System		▲1																														
(2) MS C	Thawd Blood Processing System		▲2																														
(3) MS B, (4) MS C	Ceramic Oxygen Generator System		▲3														▲4																
(5) MS C	Rotary Valve Pressure Swing Oxy Gen		▲5																														
(6) MS C	Ventilatory Assist Device		▲6																														

Schedule Detail (R4a Exhibit)						February 2005		
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 0604□0□A - Medical Materiel/Medical Biological Defense Equipm			PROJECT □32	

<u>Schedule Detail</u>	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Dental Field Treatment and Operating System (FRPND)	4Q							
Thawed Blood Processing System (MS C)			4Q					
Ceramic Oxygen Generator Systems (MS B); (MS C)			4Q		1Q			
Rotary Valve Pressure Swing Oxygen (MS B); (MS C)			3Q					
Ventilatory Assist Device (MS C)		3Q						

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5 - System Development and Demonstration

PE NUMBER AND TITLE

**0604□0□A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

□34

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
834 SOLDIER SYS PROT-ED	5693	1011	0	3030	1887	1844	1780	1778	0	17791

A. Mission Description and Budget Item Justification: This project supports system development and demonstration of preventive medicine materials to include devices, 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 Allarmed Laboratories, Inc., San Diego, CA.

Accomplishments/Planned Program	FY 2004	FY 2005	FY 2006	FY 2007
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). Leishmania Skin Test (LST): In FY04, initiated termination phase of a contract to produce and test a Leishmania Skin Test. In FY05, conduct a Critical Design Review to terminate or transition the LST to a commercial pharmaceutical company. Hepatitis E Vaccine: In FY04, fielded trial of the Hepatitis E Vaccine was completed in Nepal. In FY05, complete analysis of data from the Hepatitis E Vaccine trial and convene a Critical Design Review to transition vaccine to pivotal clinical testing. In FY06, initiate a pivotal field trial to support licensure of the Hepatitis E Vaccine. In FY 07, continue Hepatitis E Vaccine field trial.	1144	1011	0	3030
Congressional Adds in support of Chem-Bio Protection	4384	0	0	0
Small Business Innovative Research/Small Business Technology Transfer Programs	165	0	0	0
Totals	5693	1011	0	3030

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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 vaccine candidates in government-managed trials to meet FDA requirements.</p>		

ARMY RDT&E COST ANALYSIS(R3)									February 2005				
BUDGET ACTIVITY					PE NUMBER AND TITLE					PROJECT			
5 - System Development and Demonstration					060400A - Medical Materiel/Medical Biological Defense Equipm					34			
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			1834	484		0		1457		0	3775	0	
b . Congressional Add in Support of Chem-Bio Protection			4550	0		0		0		0	4550	0	
Subtotal:			6384	484		0		1457		0	8325	0	
II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			42	32		0		89		0	163	0	
Subtotal:			42	32		0		89		0	163	0	

ARMY RDT&E COST ANALYSIS(R3)									February 2005				
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 060400A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 34			
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			241	239		0		545		0	1025	0	
Subtotal:			241	239		0		545		0	1025	0	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a . No product/contract costs greater than \$1M individually			645	256		0		939		0	1840	0	
Subtotal:			645	256		0		939		0	1840	0	
Project Total Cost:			7312	1011		0		3030		0	11353	0	

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**0604□0□A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

□4□

COST (In Thousands)	FY 2004 Actual	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	FY 2010 Estimate	FY 2011 Estimate	Cost to Complete	Total Cost
849 INFEC DIS DRUG/VACC ED	3647	3392	602	3133	4063	14059	13896	3992	0	50053

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 Command's 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 Central Command, European Command, Southern Command, and Pacific Command areas) rise to the top of the requirement list.

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PROJECT

□4□

Accomplishments/Planned Program

Clinical trials, developmental testing, and appropriate reviews of malarial/antimalarial vaccines, drugs, and diagnostics: In FY04, continued the FDA-mandated Phase 1 safety trial of the Antimalarial Drug, Tafenoquine and opened an additional OCONUS site to accelerate the study; Initiated planning for studies to support licensure of Tafenoquine. In FY05, initiate two Phase 3 studies (Kenya and Indonesia planned) to evaluate effectiveness of tafenoquine; conduct a clinical design review for the RTS,S/improved adjuvant (P. falciparum); conduct a Critical Design Review to validate plan for Tafenoquine licensure and initiate planned studies. In FY06, continue Tafenoquine studies and initiate development of a licensure package for submission to the FDA. In FY07, submit licensure package to the FDA and conduct a Milestone C to transition Tafenoquine to Full-Rate Production and Deployment, providing the military with a safe, effective antimalarial drug to replace mefloquine.

FY 2004

1986

FY 2005

3021

FY 2006

519

FY 2007

3133

Prepared for conducting clinical studies, trials, and appropriate reviews of grouped vaccines, drugs, and diagnostics (Leishmaniasis, Paromomycin, Tick-borne Encephalitis Vaccine (TBEV), and Hepatitis E), which must meet stringent Environmental Protection Agency (EPA) requirements. In FY04, initiated non-clinical testing of the new camouflage face paint formulation to meet Environmental Protection Agency requirements; initiated a solicitation for contract to test and develop paromomycin topical antileishmanial cream. In FY05, complete non-clinical testing of the Camouflage Face Paint formulation and initiate planning for a Phase 1 safety study of the Combined Camouflage Face Paint/Insect Repellent (CCFP). In collaboration with industry partner, produce new formulation of the Paromomycin/ Gentamicin Topical Antileishmanial Cream and initiate clinical testing. In FY06, complete all testing required for fielding of the of the CCFP; continue phase 2/3 field testing of the Topical Antileishmanial Cream. In FY07, conduct a Milestone C and transition the CCFP to Full-Rate Production and Deployment. Conduct a Critical Design Review of the Topical Antileishmanial Cream to initiate development of licensure package for the FDA, leading to fielding of a new, far-forward treatment for cutaneous leishmaniasis.

1587

371

83

0

Small Business Innovative Research/Small Business Technology Transfer Programs

74

0

0

0

Totals

3647

3392

602

3133

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BUDGET ACTIVITY 5 - System Development and Demonstration	PE NUMBER AND TITLE 0604□0□A - Medical Materiel/Medical Biological Defense Equipm	PROJECT □4□
<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>		

ARMY RDT&E COST ANALYSIS(R3)

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BUDGET ACTIVITY

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PE NUMBER AND TITLE

**060400A - Medical Materiel/Medical Biological
Defense Equipm**

PROJECT

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I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			5791	1249		205		1063		Continue	8308	Continue
Subtotal:			5791	1249		205		1063		Continue	8308	Continue

II. Support Cost	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			440	70		71		63		Continue	644	Continue
Subtotal:			440	70		71		63		Continue	644	Continue

ARMY RDT&E COST ANALYSIS(R3)									February 2005			
BUDGET ACTIVITY 5 - System Development and Demonstration					PE NUMBER AND TITLE 060400A - Medical Materiel/Medical Biological Defense Equipm					PROJECT 4		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			8839	1506		183		1464		Continue	11992	Continue
Subtotal:			8839	1506		183		1464		Continue	11992	Continue
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2005 Cost	FY 2005 Award Date	FY 2006 Cost	FY 2006 Award Date	FY 2007 Cost	FY 2007 Award Date	Cost To Complete	Total Cost	Target Value of Contract
a . No product/contract costs greater than \$1M individually			2399	567		143		543		Continue	3652	Continue
Subtotal:			2399	567		143		543		Continue	3652	Continue
Project Total Cost:			17469	3392		602		3133		Continue	24596	Continue

Schedule Profile (R4 Exhibit)

February 2005

BUDGET ACTIVITY

5 - System Development and Demonstration

PE NUMBER AND TITLE

0604□0□A - Medical Materiel/Medical Biological
Defense Equipm

PROJECT

□4□

Event Name	FY 04				FY 05				FY 06				FY 0□				FY 0□				FY 0□				FY 10				FY 11			
	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) PBD Leishmania Skin Test					▲1																											
(2) MS B/C Promomycin/Gentamicin					▲2																											
(3) CDR RTS,S Malaria Vaccine					▲3																											
(4) MS C Malaria Rapid Diagnostic Device								▲4																								
(5) CDR Dengue Tetraivalent Vaccine								▲5																								
(6) MS C Tafenoquine Antimalarial Drug												▲6																				
(7) Down Select Complete					▲																											

Schedule Detail (R4a Exhibit)						February 2005		
BUDGET ACTIVITY 5 - System Development and Demonstration				PE NUMBER AND TITLE 060400A - Medical Materiel/Medical Biological Defense Equipm			PROJECT 4	
<u>Schedule Detail</u>	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011
Paromomycin/Gentamicin (Transition to Commercial Developer)	3-4Q							
RTS,S/improved adjuvant (P. falciparum) malaria vaccine (Critical Design Review)		1Q						
Malaria Rapid Diagnostic Device (MS C)		3Q						
Dengue tetravalent vaccine (Critical Design Review)		3Q						
Tafenoquine antimalarial drug (MS C)			3Q					