

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

February 2003

BUDGET ACTIVITY

4 - Advanced Component Development and Prototypes

PE NUMBER AND TITLE

0603807A - Medical Systems - Adv Dev

COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	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	19270	13340	11042	10012	10223	11694	13043	12545	Continuing	Continuing
808 DOD DRUG & VACC AD	3945	4882	5546	5281	5433	5367	6307	6074	Continuing	Continuing
811 MIL HIV VAC&DRUG DEV	6083	0	136	0	147	148	148	148	0	12339
836 COMBAT MEDICAL MATL AD	4070	3885	4227	3980	3691	3661	4726	4536	Continuing	Continuing
837 SOLDIER SYS PROT-AD	856	848	1133	751	952	2518	1862	1787	Continuing	Continuing
A01 COMBAT SUPPORT HOSPITAL - MOBILE SURGICAL UNIT	0	2387	0	0	0	0	0	0	0	2387
MD4 FUTURE MEDICAL SHELTER	3358	1338	0	0	0	0	0	0	0	4696
MD5 IMED TOOLS RURAL MOBILE COMMS	958	0	0	0	0	0	0	0	0	958

A. Mission Description and Budget Item Justification: This program element (PE) funds advanced development of medical materiel within the early-on system integration within the System Development and Demonstration portion of the acquisition life cycle. The PE supports the transition of Science and Technology initiatives, prototypes, or candidate technologies into the first scale-up, integrated models for initial test and evaluation both technically and operationally when applicable. These programs have been aligned to meet Objective Force (OF) requirements stressed within the concept documents and organizational structures. The PE provides funding for early Phase 1 and 2 Food and Drug Administration regulated human clinical trials. The major enablers that will be supported by this PE are:

Infectious disease vaccines and preventive drugs that will reduce the risk of service members contracting these debilitating or fatal diseases, especially within a battlefield of growing potentials as urban warfare risks increase. Disease and non-battle injury (DNBI) rates are the largest contributor to medical footprint, and reduction in ill patients could have a significant reduction in echelon 3 facilities. Equally important, the reduction of patient evacuation within OF 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 OF 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 their supported maneuver units.

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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.

Military HIV Vaccine and Drug Development – Funds militarily relevant HIV medical countermeasures including advanced component development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials.

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

This program supports the OF transition path of the Transformation Campaign Plan (TCP).

There are no Defense Emergency Response Funds provided to this program or project.

<u>B. Program Change Summary</u>	FY 2002	FY 2003	FY 2004	FY 2005
Previous President's Budget (FY 2003)	19872	10398	10245	11309
Current Budget (FY 2004/2005 PB)	19270	13340	11042	10012
Total Adjustments	-602	2942	797	-1297
Congressional program reductions				
Congressional rescissions		-584		
Congressional increases		3900		
Reprogrammings	-139	-88		
SBIR/STTR Transfer	-463	-286		
Adjustments to Budget Years			797	-1297

Change Summary Explanation: Funding – FY 2004 increase to support accelerated product development in combat casualty care and infectious diseases to meet OF timelines, and the Army TCP. FY 2005 funds realigned in support of higher priority programs.

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BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 808		
COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
808 DOD DRUG & VACC AD	3945	4882	5546	5281	5433	5367	6307	6074	Continuing	Continuing
<p><u>A. Mission Description and Budget Item Justification:</u> This project funds technical development of candidate medical countermeasures to infectious diseases that occur within military relevant areas of the world. These products fall within three major areas: vaccines, drugs, and diagnostic kits. The funds support Phase 1 and 2 human clinical trials for safety, immunogenicity, and small-scale efficacy testing. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis if contracted, and speed recovery once diagnosed. These trials are required to meet 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). The reduction in risk to contract infectious diseases within the force supports the Army Transformation Campaign Plan (TCP) and directly enables the Objective Force (OF) concept through reduction of evacuations of uniquely qualified soldiers and decrease in medical footprint to sustain these evacuees.</p> <p>Major contractors include: Southern Research Institute, Birmingham AL; Iguana L.L.C., Thomasville, GA; and Kenya Medical Research Institute, Nairobi, Kenya.</p> <p>There are no Defense Emergency Response Funds provided to this program or project.</p>										

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)			February 2003			
BUDGET ACTIVITY		PE NUMBER AND TITLE			PROJECT	
4 - Advanced Component Development and Prototypes		0603807A - Medical Systems - Adv Dev			808	
Accomplishments/Planned Program			FY 2002	FY 2003	FY 2004	FY 2005
Reviews, evaluations, and trials of malarial/anti-malarial vaccines, drugs, and diagnostics: In FY02, conducted Phase 1 clinical trial of new dose regimen of RTS,S malaria vaccine with a new adjuvant (immune enhancer); conducted first year of a multiyear Phase 2 safety and efficacy trial with RTS,S in Kenya; successfully completed developmental testing of prototype kits that will be used by preventive medicine teams for rapid detection of Plasmodium-infected mosquitoes; conducted Milestone (MS) B/C for the rapid detection of Plasmodium-infected mosquitoes. In FY03, conduct true negative trials with the Malaria Rapid Diagnostic Device (MRDD); continue a Phase 2 safety and efficacy trial with RTS,S P. falciparum vaccine in U.S. volunteers; conduct a MS B In Process Review (IPR) for MRDD. In FY04, transition the MRDD to full-rate production and deployment.			791	732	388	0
Clinical trials, safety evaluations, and reviews of diarrheal vaccines: In FY02, completed Phase 2 safety and efficacy field trial for Shigella flexneri vaccine in Bangladesh. In FY03, plan to conduct a program initiation IPR for the Shigella sonnei vaccine; complete Phase 2 clinical efficacy evaluation of Shigella sonnei vaccine for the prevention of traveler's diarrhea. In FY04, conduct a program initiation/MS B IPR and a Phase 1 clinical safety evaluation of the Shigella dysenteriae vaccine; conduct a Phase 2 efficacy trial in U.S. volunteers of the Shigella flexneri vaccine, conduct a MS B IPR for Shigella flexneri vaccine. In FY05, conduct a Phase 2 safety and efficacy study with Shigella dysenteriae vaccine; complete a Phase 2 efficacy trial of the Shigella flexneri vaccine in Americans.			150	1123	1719	2376

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BUDGET ACTIVITY		PE NUMBER AND TITLE			PROJECT	
4 - Advanced Component Development and Prototypes		0603807A - Medical Systems - Adv Dev			808	
Accomplishments/Planned Program (continued)			FY 2002	FY 2003	FY 2004	FY 2005
Trials, evaluations, and reviews for grouped infectious disease vaccines and drugs (Hepatitis E and Leishmania): In FY02, continued a multiyear Phase 2 field trial in Nepal to evaluate the effectiveness of the Hepatitis E vaccine; produced Phase 1 and Phase 2 Good Manufacturing Practices (GMP) test kits; conducted a Phase 1 safety trial for the Leishmania mexicana skin test kits; continued to conduct Phase 2 clinical trial of paromomycin/gentamicin topical antileishmanial cream to treat Old World leishmaniasis. In FY03, continue a multiyear Phase 2 field trial in Nepal to evaluate the effectiveness of Hepatitis E vaccine; conduct a MS B IPR for the Leishmania skin test kits; submit a new Investigational New Drug (IND) for GMP L. tropica skin test kits and prepare for Phase 1 safety trial with industry partner's Leishmania skin test kits; continue the Phase 2 clinical trial of paromomycin/gentamicin topical antileishmanial cream to treat Old World leishmaniasis. In FY04, complete the multiyear Phase 2 trial in Nepal to evaluate the Hepatitis E vaccine; conduct a MS B on the Hepatitis E vaccine; complete the Phase 2 field trial of the topical antileishmanial cream; transition the topical antileishmanial cream to a co-development partner; complete phase 1 safety trial with Leishmania skin test kits. In FY05, conduct a MS B/C for the topical antileishmanial cream; begin a Phase 2 field trial in Turkey to evaluate safety and efficacy of the L. tropica skin test.			1458	2002	2274	634
In FY02, challenged previously dengue tetravalent vaccinated volunteers with dengue 1 and 2 challenge virus strains; identified a dengue 4 challenge strain for future challenge studies; conducted Phase 1 safety trial with the leading dengue tetravalent live-attenuated vaccine formulation and began production and testing of master vaccine seeds (source of all subsequent tetravalent vaccine components). In FY03, conduct a Phase 1b dengue vaccine pediatric trial and begin a 5-year follow-up; continue production and testing of master dengue vaccine seeds; conduct a Phase 2 study in a dengue endemic area (Costa Rica); conduct second dengue challenge study in additional tetravalent vaccinated volunteers. In FY04, conduct a Phase 2 study in second dengue endemic area (Peru); complete production and testing of master vaccine seeds. In FY05, conduct program initiation IPR and transition an alternative vaccine technology (DNA-based dengue vaccine) to advanced development.			1072	830	1165	2271
Developmental test and evaluation, and reviews of insect vector control products: In FY02, completed developmental testing of camouflage face paint with insect repellent and visual infrared signature and conducted MS B/C IPR. In FY03, complete developmental testing of a prototype lethal trap for dengue vectors; conduct MS B/C IPR for the lethal trap for dengue vectors program; conduct preplanned product improvement to develop new dispensers for camouflage face paint with insect repellent and reduced infrared signature.			474	195	0	0

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PROJECT

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<u>Accomplishments/Planned Program (continued)</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>
Totals	3945	4882	5546	5281

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

C. Acquisition Strategy: Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and Environmental Protection Agency registration.

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 808		
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			2943	889		997		947		Continue	Continue	Continue
Subtotal:			2943	889		997		947		Continue	Continue	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			394	53		59		56		Continue	Continue	Continue
Subtotal:			394	53		59		56		Continue	Continue	Continue

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 808		
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			9855	3100		3551		3387		Continue	Continue	Continue
Subtotal:			9855	3100		3551		3387		Continue	Continue	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			2095	840		939		891		Continue	4765	0
Subtotal:			2095	840		939		891		Continue	4765	0
Project Total Cost:			15287	4882		5546		5281		Continue	Continue	Continue

Schedule Profile Detail (R-4a Exhibit)						February 2003		
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes			PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 808	
<u>Schedule Detail</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Leishmania Skin Test (MS B)					4Q			
Shigella flexneri (MS B)			3Q					
Paromomycin/Gentamicin (MS B/C)				1Q				
Hepatitis E vaccine (MS B)		3Q						
RTS,S malaria vaccine (MS B)		2Q						
Malaria Rapid Diagnostic Device (MS B)		2Q						
Camouflage face paint (MS B) (Repellent: Thermal)		2Q						
Dengue tetravalent vaccine (MS B)			1Q					
Detection of Plasmodium-infected mosquitoes (MS B/C)	3Q							
Shigella sonnei vaccine (Program Initiation IPR)		4Q						
Shigella dysenteriae vaccine (Program Initiation IPR/MS B)			3Q					
DNA based dengue tetravalent vaccine (Program Initiation IPR)				1Q				

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BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 836		
COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
836 COMBAT MEDICAL MATL AD	4070	3885	4227	3980	3691	3661	4726	4536	Continuing	Continuing
<p><u>A. Mission Description and Budget Item Justification:</u> 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 funds Phase 1 and 2 human clinical trials for safety and efficacy of devices or biologics unique to military operational requirements. These products will decrease mortality rates thereby increasing soldier morale and willingness to place themselves in danger. Additionally, several products 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 positively support both the Army Transformation Campaign Plan (TCP) and Objective Force (OF) doctrine/organizational structure.</p> <p>Major contractors/intragovernmental agencies include: Army Medical Department Test Board, American National Red Cross, Cambridge Consultants Corporation, IGR Enterprises, Madigan Army Medical Center, and Sequal.</p> <p>There are no Defense Emergency Response Funds provided to this program or project.</p>										
<u>Accomplishments/Planned Program</u>							FY 2002	FY 2003	FY 2004	FY 2005
Hemostatic Dressing (HD): In FY02, conducted animal trials required by the U.S. Food and Drug Administration (FDA) and prepared Investigational New Drug application for FDA. In FY03, continue testing of the HD and prepare for a Milestone (MS) B In Process Review (IPR). In FY04, conduct elective surgery trials (human clinical trials) using informed consent, and conduct a MS B IPR. In FY05, continue elective surgery trials (human clinical trials) using informed consent, and prepare Biologics License Application.							2020	1565	2828	2870
Demonstrate, evaluate, and continue to develop medical evacuation systems. Special Medical Emergency Evacuation Device (SMEED): In FY02, developed and fabricated 15 prototypes and began user evaluations. In FY03, continue user evaluations, complete manuals and Air Worthiness Release (including crash testing), conduct a MS C IPR, and field basic systems.							302	525	0	0

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)		February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes		PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev		PROJECT 836	
<u>Accomplishments/Planned Program (continued)</u>		FY 2002	FY 2003	FY 2004	FY 2005
Conduct/Perform development, testing and Milestone IPRs for field medical treatment and treatment aid devices. (1) Ceramic Oxygen Generator System (COGS): In FY02, scaled up oxygen generator cells from test sizes to full size, approximately a 10-fold increase in area. (2) Ventilatory Assist Device (VAD): In FY02, demonstrated compatibility of anesthesia machines with oxygen concentrators, and validated minimum safe oxygen flow rates for circle breathing systems using oxygen concentrators. In FY03, develop an FDA-approved anesthetic agent scrubber that will not require exterior venting, and conduct clinical use and evaluation of the completed anesthesia system at 10 Army Medical Treatment Facilities. In FY04, conduct a MS B/C IPR. (3) Pressure Swing Adsorption Oxygen Generator (PSAOC): In FY02, designed, built, and incorporated the prototype high-speed turbo compressor and electric motor into an oxygen generator with molecular sieve beds. (4) Dental Field Treatment and Operating System (DEFTOS): In FY02, conducted a MS A/Program Initiation IPR and worldwide user evaluation. In FY03, redesign to reflect test results and conduct limited testing. (5) One-Handed Tourniquet (OHT): In FY02, fabricated protocols and initiated technical evaluations of prototype. In FY03, procure additional samples for a large-scale user evaluation and conduct a MS B IPR. (6) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY02, contracted for development of a lightweight portable RVPSAOG. In FY03, complete prototype of the system and conduct a MS A IPR. In FY04, conduct user evaluation and prepare a MS B/C package. In FY05 conduct the MS B/C IPR.		1748	1795	1399	1110
Totals		4070	3885	4227	3980
<p><u>B. Other Program Funding Summary:</u> Not applicable for this item.</p> <p><u>C. Acquisition Strategy:</u> Evaluate commercially developed materiel in government-managed tests for hardening or other modification.</p>					

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 836		
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, N.C.	3768	1940		2828		2870		Continue	Continue	0
b . No other contract exceeds \$1M			11824	0		0		0		0	11824	0
Subtotal:			15592	1940		2828		2870		Continue	Continue	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
Subtotal:			0	0		0		0		0	0	0
Remarks: No product/contract costs greater than \$1M individually.												

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 836		
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
			0	0		0		0		0	0	0
Subtotal:												
Remarks: No product/contract costs greater than \$1M individually.												
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 \$M individually.			4436	1945		1399		1110		0	8890	0
Subtotal:			4436	1945		1399		1110		0	8890	0
Project Total Cost:			20028	3885		4227		3980		Continue	Continue	0

Schedule Profile Detail (R-4a Exhibit)							February 2003	
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 836
<u>Schedule Detail</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Hemostatic Dressing (MS B)			2Q					
SMEED (MS C)		4Q						
Oxygen Generator Systems (MS B)			2Q					
One-Handed Tourniquet (MS C)		4Q						
Dental Field Treatment and Operating System (MS B)	4Q							
Ventilatory Assist Device (MS B/C)			2Q					

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)								February 2003		
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev				PROJECT 837		
COST (In Thousands)	FY 2002 Actual	FY 2003 Estimate	FY 2004 Estimate	FY 2005 Estimate	FY 2006 Estimate	FY 2007 Estimate	FY 2008 Estimate	FY 2009 Estimate	Cost to Complete	Total Cost
837 SOLDIER SYS PROT-AD	856	848	1133	751	952	2518	1862	1787	Continuing	Continuing
<p><u>A. Mission Description and Budget Item Justification:</u> This project supports concept and technical development 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. Major advanced development contractors include Allarmed Laboratories, San Diego, CA. This program supports the Objective Force transition path of the Transformation Campaign Plan (TCP).</p> <p>There are no Defense Emergency Response Funds provided to this program or project.</p>										
<u>Accomplishments/Planned Program</u>						<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	
In FY02, resolved the technical issues raised by the U.S. Food and Drug Administration (FDA) on the manufacture of the skin test for Leishmania mexicana, which causes leishmaniasis in the Americas and conducted a Phase 1 safety trial; established the good manufacturing practices (GMP) manufacturing line for the skin test for L. tropica skin test, which causes leishmaniasis in Southwest Asia. In FY03, produce the FDA-required three-lot consistency lots of the L. tropica skin test and conduct a Phase 1 safety trial. In FY04, conduct stability studies on the three lots of L. tropica skin tests, and manufacture the skin tests for the Phase 3 pivotal studies to be conducted in Turkey. In FY05, continue the stability testing of the original three lots, start the stability testing on the skin tests made for the Phase 3 study, and begin a Phase 2 field trial with the L. tropica skin test.						856	848	1133	751	
Totals						856	848	1133	751	

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BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes	PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev	PROJECT 837
<p><u>B. Other Program Funding Summary:</u> Not applicable for this item.</p> <p><u>C. Acquisition Strategy:</u> Test and evaluate materiel in government-managed trials to meet fielding requirements.</p>		

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 837		
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			359	384		498		331		Continue	Continue	0
Subtotal:			359	384		498		331		Continue	Continue	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			20	21		26		18		Continue	Continue	0
Subtotal:			20	21		26		18		Continue	Continue	0

ARMY RDT&E COST ANALYSIS(R-3)									February 2003			
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes					PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev					PROJECT 837		
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		Research and development; stability and potency testing	88	89		115		77		Continue	Continue	0
Subtotal:			88	89		115		77		Continue	Continue	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			389	354		494		325		Continue	Continue	0
Subtotal:			389	354		494		325		Continue	Continue	0
Project Total Cost:			856	848		1133		751		Continue	Continue	0

Schedule Profile Detail (R-4a Exhibit)						February 2003		
BUDGET ACTIVITY 4 - Advanced Component Development and Prototypes				PE NUMBER AND TITLE 0603807A - Medical Systems - Adv Dev			PROJECT 837	
<u>Schedule Detail</u>	<u>FY 2002</u>	<u>FY 2003</u>	<u>FY 2004</u>	<u>FY 2005</u>	<u>FY 2006</u>	<u>FY 2007</u>	<u>FY 2008</u>	<u>FY 2009</u>
Leishmania Skin Test (MS B); (MS C)					4Q			2Q