

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

May 2009

BUDGET ACTIVITY  
**4 - Advanced Component Development and Prototypes** PE NUMBER AND TITLE  
**0603807A - Medical Systems - Adv Dev**

COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
Total Program Element (PE) Cost	25207	30207	31275	Continuing	Continuing
808 DOD DRUG & VACC AD	4413	5649	6865	Continuing	Continuing
811 MIL HIV VAC&DRUG DEV	145	149	1468	Continuing	Continuing
836 Field Medical Systems Advanced Development	3160	13671	22942	Continuing	Continuing
837 SOLDIER SYS PROT-AD	1837	6751		Continuing	Continuing
A01 COMBAT SUPPORT HOSPITAL - MOBILE SURGICAL UNIT	5796				
CS4 MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	6376	3987			10363
MD4 FUTURE MEDICAL SHELTER	1932				1932
MD8 ELECTROSOMOTIC PAIN THERAPY SYSTEM (CA)	1548				1548

**A. Mission Description and Budget Item Justification:** This program element (PE) funds development of medical materiel at the start of an official program of record, within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet Future Force (F2) requirements stressed within concept documents and organizational structures. The PE provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans. The major enablers supported by this PE are:

Combat Casualty Care devices and biologics (products derived from living organisms), with two major focuses: 1) enhance forward care at the first responder level while reducing the footprint of medical organizations for greater mobility and easier sustainment, and 2) provide enhanced post-evacuation care and rehabilitation. The F2 concept places Soldiers into a more austere environment with lengthened evacuation times (both arrival and transit). Supporting medics and first responders require greater lifesaving and extended stabilization capability to save lives.

Soldier Performance Enhancers in the form of drugs and diagnostics will allow commanders to manage a Soldier's mental and physical performance. Performance enhancers will increase Soldier capabilities and reduce casualties resulting from high operational tempo, extreme environmental exposure, and loss of cognitive ability.

Infectious disease efforts include testing candidate vaccines and preventive and therapeutic drugs to reduce the risk of service members contracting debilitating or fatal diseases, and/or to shorten recovery time. Technologies for identifying disease threats and mechanisms for controlling disease-carrying insects will reduce risk of exposure. Disease and non-battle injuries (DNBI) are the largest contributors to the combat support hospital footprint, and significant reductions of the medical footprint in theater can be achieved by

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reducing the number of DNBI affected Soldiers.

Military Human Immunodeficiency Virus (HIV) Vaccine and Drug Development funds militarily relevant HIV medical countermeasures. These include component development of candidate vaccines for large-scale field testing.

This program is managed by U.S. Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the US Army Medical Research and Materiel Command.

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<u><b>B. Program Change Summary</b></u>	FY 2008	FY 2009	FY 2010
Previous President's Budget (FY 2009)	29689	26308	24537
Current BES/President's Budget (FY 2010)	25207	30207	31275
Total Adjustments	-4482	3899	6738
Congressional Program Reductions	-190	-101	
Congressional Rescissions			
Congressional Increases		4000	
Reprogrammings	-3541		
SBIR/STTR Transfer	-751		
Adjustments to Budget Years			6738

Change Summary Explanation: Funding:  
 In FY08, the congressional add of \$1.2 Million for Pneumothorax Detection Device was reprogrammed from PE 0603807 to PE 0603002. The balance was reprogrammed to higher priority program.  
 Increases of \$4 million in FY 09 due to Congressional adds:  
 In FY09 project Leishmania Skin Test \$.8 Million  
 In FY09 project Garment-Based Physiological Monitoring System \$1.6 Million  
 In FY09 project Wireless Medical Monitoring System (WiMed) \$1.6 Million  
 In FY10 funding increase due to POM Plus up to re-baseline funding.

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>808</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
808 DOD DRUG & VACC AD	4413	5649	6865	Continuing	Continuing

**A. Mission Description and Budget Item Justification:** This project funds development of candidate medical countermeasures for infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/devices, and insect control measures. These funds support human clinical efficacy (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works, and to continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat 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).

<u>Accomplishments/Planned Program:</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Reviews, evaluations, and human clinical trials of malarial/anti-malarial vaccines, drugs, diagnostics and insect repellents: In FY08, for the anti-malarial drug, Tafenoquine (for treatment and post-exposure of Plasmodium vivax malaria), completed the Integrated Safety Output document and prepared a report on the expanded safety trial. For Artesunate (anti-malarial drug), continued human efficacy trials and conducted a Critical Design Review (CDR) and reduced efforts to monitoring progress of industry partner) as they have the lead for preparing the FDA licensure package for Artesunate. Completed the analysis for Combined Camouflage Face Paint/Insect Repellent (CCFP) new stick formulations evaluated in a field efficacy trial and reported on compatibility of the CCFP with insect repellent formulation against textile materials and equipment items and transition to project 849. In FY09, for Tafenoquine, begin development/validation of new laboratory assay to determine levels of antibodies from malaria infection using blood samples from a mefloquine (current FDA-approved malaria drug) challenge clinical study (supported by project 849) and will evaluate potential sites for future human safety/efficacy trial, and conduct a Critical Design Review (CDR). The Artesunate drug will transition from project 810 and a Critical Design Review (CDR) will be conducted. In FY10, for Tafenoquine, will down-select to best site for human safety/efficacy trial and will continue laboratory assay development/validation to understand the human body's immune responses when infected with malaria parasites and as tool for determining future clinical trial enrollment size, and will transition the entire Tafenoquine program to project 849. Will monitor progress of a new military topical insect repellent candidate in project 810 to determine its suitability for entry into advanced development. For the Infectious Disease Diagnostic (Multiple candidates), conduct market	1932	1875	1921
research of selected developmental and commercial diagnostic platforms for select infectious diseases of military interest to determine suitability for entry into advanced development.			
Trials, evaluations, and reviews for grouped infectious disease (Dengue [a severe debilitating disease caused by a virus and transmitted by a mosquito] and Leishmania [a skin-based disease caused by a parasite and transmitted by sand flies]) vaccines and drugs: In FY08, the Dengue Tetravalent Vaccine (DTV), monitored progress of the expanded safety/efficacy trial in Puerto Rico and continued	2481	3661	4944

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

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT	
<b>4 - Advanced Component Development and Prototypes</b>	<b>0603807A - Medical Systems - Adv Dev</b>	<b>808</b>	
<p>enrollment/follow-up in the Thailand human safety trials. The Paromomycin/Gentamicin Topical Antileishmanial Cream, began enrollment in the pivotal safety/efficacy trial in Tunisia and continued stability testing of the cream. For Pentostam (intravenous drug treatment of skin lesions caused by the Leishmania parasite), monitored industry partner's progress in preparing the FDA licensure package. The Congressional-interest Leishmania Skin Test (LST), finalized the clinical report for the human clinical trial for safety and effectiveness, submitted a human clinical trial safety study (in the United States) protocol for human use review, and continue stability studies of the product. In FY09, The DTV vaccine will continue FDA required vaccine potency and stability testing of the product and all other DTV activities are transitioned to project 849. The Topical Antileishmanial Cream, open a human treatment protocol in the U.S., the industry partner will continue stability testing and produce new clinical drug lots, and project 849 supports the overseas human trials activities of this topical cream. The LST, will complete follow-up and perform data analysis for the expanded human safety/dose ranging/sensitization trial in the U.S. and conduct a Critical Design Review (CDR). The Pentostam drug transitions to project 849. In FY10, DTV vaccine will continue FDA required vaccine potency and stability testing and all other DTV activities are transitioned to project 849. For the Topical Antileishmanial Cream, will continue a human treatment protocol in the U.S., the industry</p>			
<p>partner will continue stability testing and produce new clinical drug lots, and project 849 supports the overseas human clinical trials activities of this topical cream. For LST, will complete the final report for the expanded human safety/dose ranging/sensitization trial in the U.S., and conduct pre-trial activities for a large scale (&gt;200 subjects) human safety/efficacy trial in a Leishmania endemic region.</p>			
Small Business Innovative Research/Small Business Technology Transfer Programs.		113	
Total		4413	6865

**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 (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
4 - Advanced Component Development and Prototypes			0603807A - Medical Systems - Adv Dev							808		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			5952	545		1412		1750		Cont.	Cont.	Cont.
Subtotal:			5952	545		1412		1750		Cont.	Cont.	Cont.
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			1401	182		1130		1289		Cont.	Cont.	Cont.
Subtotal:			1401	182		1130		1289		Cont.	Cont.	Cont.
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			33699	2757		2090		2574		Cont.	Cont.	Cont.
Subtotal:			33699	2757		2090		2574		Cont.	Cont.	Cont.
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			7197	929		1017		1252		Cont.	Cont.	
Subtotal:			7197	929		1017		1252		Cont.	Cont.	

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>	PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>						PROJECT <b>808</b>			
<b>Project Total Cost:</b>	<b>48249</b>	<b>4413</b>		<b>5649</b>		<b>6865</b>		<b>Cont.</b>	<b>Cont.</b>	<b>Cont.</b>

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY		PE NUMBER AND TITLE																PROJECT														
<b>4 - Advanced Component Development and Prototypes</b>		<b>0603807A - Medical Systems - Adv Dev</b>																<b>808</b>														
Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	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
Anti-Malarial, Tafenoquine (CDR)	Critical Design Review				▲ <sub>0</sub>																											
Antimalarial, Artesunate (CDR)	Critical Design Review				▲ <sub>0</sub>																											
Leishmania Skin Test (CDR)	Critical Design Review				▲ <sub>0</sub>																											
New Standard Military Topical Insect Repellant (MS-B)													MS-B ▲ <sub>0</sub>																			

# Schedule Detail (R4a Exhibit)

May 2009

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>		PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>					PROJECT <b>808</b>	
<u>Schedule Detail</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>	<u>FY 2014</u>	<u>FY 2015</u>
Anti-Malarial, Tafenoquine (CDR)		1Q						
Antimalarial, Artesunate (CDR)	4Q							
Leishmania Skin Test (CDR)		2Q						
New Standard Military Topical Insect Repellant (MS-B)				2Q				

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>		<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>811</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost	
811 MIL HIV VAC&DRUG DEV	145	149	1468	Continuing	Continuing	

**A. Mission Description and Budget Item Justification:** This project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides for the planning and conduct of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and to investigate the appropriate dose for therapeutic use. Development efforts are focused on militarily unique needs effecting manning, mobilization, and deployment.

The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.

<u>Accomplishments/Planned Program:</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
In FY10, will evaluate and down-select potential commercial drug/vaccine candidates for preliminary human trials and conduct Design Readiness Review (DRR).	145	145	1468
Small Business Innovative Research/Small Business Technology Transfer Programs		4	
<b>Total</b>	<b>145</b>	<b>149</b>	<b>1468</b>

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

**C. Acquisition Strategy** Test and evaluate commercially developed drug/vaccine candidates in government-managed trials.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
4 - Advanced Component Development and Prototypes			0603807A - Medical Systems - Adv Dev							811		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Product Development	Cooperative Agreement	Henry M. Jackson Foundation, Rockville, MD	5139					347		Cont.	Cont.	
Subtotal:			5139					347		Cont.	Cont.	
Remarks: Not Applicable												
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			868	145		149		202			1961	
Subtotal:			868	145		149		202			1961	
Remarks: Not Applicable												
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Test and Evaluation	Government Laboratory	U.S. Component AFRIMS, Bangkok, APO, AP 96546-5000	11495					705			13307	
Subtotal:			11495					705			13307	
Remarks: Not Applicable												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually.			250					214			464	

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY		PE NUMBER AND TITLE						PROJECT	
<b>4 - Advanced Component Development and Prototypes</b>		<b>0603807A - Medical Systems - Adv Dev</b>						<b>811</b>	
Subtotal:		250				214		464	
Remarks: Not Applicable									
<b>Project Total Cost:</b>		<b>17752</b>	<b>145</b>		<b>149</b>		<b>1468</b>	<b>Cont. Cont.</b>	

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT																														
<b>4 - Advanced Component Development and Prototypes</b>	<b>0603807A - Medical Systems - Adv Dev</b>	<b>811</b>																														
Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	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
HIV Vaccine Design Readiness Review (DRR)																																



**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>		PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>					PROJECT <b>811</b>	
<u>Schedule Detail</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>	<u>FY 2014</u>	<u>FY 2015</u>
HIV Vaccine Design Readiness Review (DRR)			4Q					

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>	<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>836</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
836 Field Medical Systems Advanced Development	3160	13671	22942	Continuing	Continuing

**A. Mission Description and Budget Item Justification:** This project funds development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. When available, commercially-off-the-shelf (COTS) medical products are also tested and evaluated for transition to system development and demonstration. Consideration is also given to reducing the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. Food and Drug Administration (FDA) regulations.

In FY10 Project 837 Soldier Sys Prot-AD will be consolidated into this Project, 836.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; SeQual Technologies, Inc.; Ultrasonic Diagnostics, Inc.; HemCon Medical Technologies, Inc.; Hemerus Medical, LLC.; Fast Track Drugs & Biologics, LLC; Clinical Research Management, and Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation.

<u>Accomplishments/Planned Program:</u>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
(1) Ceramic Oxygen Generator (COG): In FY08, completed development of new prototype to satisfy form and fit requirements. In FY09, transition to project 832 for Systems Development and Demonstration.(2) Rotary Valve Pressure Swing Adsorption Oxygen Generator (RVPSAOG): In FY08 conducted technical testing of Omni II and fully transitioned to project 832 for Systems Development and Demonstration. (3) Future Medical Shelter System (FMSS): In FY08, developed engineering development models. In FY09, down-select to one system. In FY10, procure one system for the Force Provider Early Entry Combat Support Hospital (CSH). (4) Future Combat System (FCS): In FY09, prepare for performance design review (PDR), and provide support to PM-Future Combat Systems Brigade Combat Team regarding Medical Mission package, treatment table, shelter, and patient movement items for form, fit, and function. In FY10 will support PM-FCS with building first prototypes for testing.(5) Ultrasonic Brain Imager (UBI): In FY08, finished technical testing and evaluation of prototype resolution and capabilities. In FY09, begin clinical user assessments, based on a down-select. In FY10, transition to project 832 for Systems Development and Demonstration(6) Freeze-dried Plasma Program (hemorrhage treatment candidate): In FY08 began pre-clinical trial activities for a safety/efficacy human clinical trial with new lots of freeze-dried plasma. In FY09, transition to project 832 for Systems Development and Demonstration. (7) Red Blood Cell Extended Life (RBCXL) program (hemorrhage treatment candidate - a new blood collection and storage system that extends the shelf-life of red blood cells from 6 to 8 weeks): In FY08, was supported by Department of Defense Technology Transition Initiative (TTI) Program that matured the blood collection and storage system to a	3160	13341	22942
viable candidate for transition to advanced development. In FY09 transition to project 832.(8) Platelet Derived Hemostatic Agent (PDHA) (use of cryopreserved platelets for control of severe bleeding): In FY08 monitored the establishment of a stable manufacturing procedure for frozen platelets (supported by project 840) that allowed for future refinement of a good manufacturing process to meet FDA			

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BUDGET ACTIVITY	PE NUMBER AND TITLE	PROJECT	
<b>4 - Advanced Component Development and Prototypes</b>	<b>0603807A - Medical Systems - Adv Dev</b>	<b>836</b>	
requirements and to provide for future clinical evaluations. In FY09, begin a feasibility clinical evaluation and conduct good manufacturing practices validation studies of the product. In FY10, will complete data analysis of feasibility clinical evaluation and prepare final report, will begin a safety/efficacy clinical study, and will establish good manufacturing practices' process at military blood centers for human studies support, and transition to project 832 for Systems Development and Demonstration.(9) Intranasal Ketamine (low dose pain management via nasal spray): In FY09, will conduct a Pain Management Meeting with Combat Developer (representing Military requirements) and medical caregivers across roles of care to determine which pain management options are best for deployed hospitals, during medical evacuation, and at far forward treatment facilities in austere environments. In FY10, will conduct human trial to assess intranasal ketamine drug effects on a subject's judgment. (10) Antiplatelet Gum: In FY10 will transition from project 840 and will conduct small human safety and dose escalation study in health adults. (11) Environmental Sentinel Biomonitor (ESB). In FY10, transition increment 1 from project 837 and increment 2 from technology			
development project FH4, initiate development of increment 2 ESB system for use in conjunction with field water facilities.			
Small Business Innovative Research/Small Business Technology Transfer Programs		330	
Total	3160	13671	22942

**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)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
4 - Advanced Component Development and Prototypes			0603807A - Medical Systems - Adv Dev								836	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Clinical Research Management		Hinckley, OH									1133	
Allied Technologies & Consulting LLC		Frederick, MD				1785		1580			5365	
Aquila Alaska Corporation		Wasilla, AK				1200					1200	
SeQual Technologies		San Diego, CA				1100					1100	
No other contract exceeds \$1M			15169	87				5449			20705	
Subtotal:			15169	87		4085		7029			29503	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually						2734		4343			13527	
Subtotal:						2734		4343			13527	
Remarks: No product/contract costs greater than \$1M individually.												
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$M individually.						5058		8033			22352	
Subtotal:						5058		8033			22352	
Remarks: No product/contract costs greater than \$1M individually.												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award	FY 2009 Cost	FY 2009 Award	FY 2010 Cost	FY 2010 Award	Cost To Complete	Total Cost	Target Value of

# ARMY RDT&E COST ANALYSIS (R3)

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BUDGET ACTIVITY			PE NUMBER AND TITLE						PROJECT		
<b>4 - Advanced Component Development and Prototypes</b>			<b>0603807A - Medical Systems - Adv Dev</b>						<b>836</b>		
	Type				Date		Date		Date		Contract
No product/contract costs greater than \$M individually.			28754	3073		1794		3537			37158
Subtotal:			28754	3073		1794		3537			37158
<b>Project Total Cost:</b>			<b>43923</b>	<b>3160</b>		<b>13671</b>		<b>22942</b>			<b>102540</b>

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY  
**4 - Advanced Component Development and Prototypes**

PE NUMBER AND TITLE  
**0603807A - Medical Systems - Adv Dev**

PROJECT  
**836**

Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	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
Future Combat Systems (CDR)																																

**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>		PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>					PROJECT <b>836</b>	
<u>Schedule Detail</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>	<u>FY 2014</u>	<u>FY 2015</u>
Future Combat Systems (CDR)		4Q						

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>		<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>837</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost	
837 SOLDIER SYS PROT-AD	1837	6751		Continuing	Continuing	

**A. Mission Description and Budget Item Justification:** This project funds development of preventive medicine materiel, including devices and medicines, in order to provide protection, sustainment, and enhancement of the physical and psychological capabilities of Soldiers across the Army's full spectrum operations. Focus is on the 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.

In FY10, Project 837 will be consolidated into Project 836 Combat Medical Matl AD.

Major contractors are Pacific Technologies, Inc, Redwood, WA, and Agave Biosystems Inc, Austin, TX.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Coliform Analyzer: In 4Q FY08, conducted user tests and evaluations and milestone B for transition to System Development and Demonstration. In FY09, conduct technical testing and user evaluation and transition to project 834 for System Development and Demonstration. Environmental Sentinel Biomonitor (ESB): In 2Q FY09, conduct Milestone B (for increment 1 ESB system). In FY10, project 837 is consolidated into project 836.	1837	6562	
Small Business Innovative Research/Small Business Technology Transfer Programs		189	
<b>Total</b>	1837	6751	

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

**C. Acquisition Strategy** Test and evaluate materiel in-house and commercially developed preventative medicine materiel to meet FDA and EPA regulatory requirements.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE							PROJECT		
<b>4 - Advanced Component Development and Prototypes</b>			<b>0603807A - Medical Systems - Adv Dev</b>							<b>837</b>		
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			3661	863		3228				Cont.	Cont.	
Subtotal:			3661	863		3228				Cont.	Cont.	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			247	57		205				Cont.	Cont.	
Subtotal:			247	57		205				Cont.	Cont.	
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually		Research and development; stability and potency testing	1276	309		1205				Cont.	Cont.	
Subtotal:			1276	309		1205				Cont.	Cont.	
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
No product/contract costs greater than \$1M individually			2472	608		2113				Cont.	Cont.	

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY	PE NUMBER AND TITLE						PROJECT		
<b>4 - Advanced Component Development and Prototypes</b>	<b>0603807A - Medical Systems - Adv Dev</b>						<b>837</b>		
Subtotal:	2472	608		2113			Cont.	Cont.	
<b>Project Total Cost:</b>	<b>7656</b>	<b>1837</b>		<b>6751</b>			<b>Cont.</b>	<b>Cont.</b>	

# Schedule Profile (R4 Exhibit)

May 2009

BUDGET ACTIVITY	PE NUMBER AND TITLE																PROJECT															
<b>4 - Advanced Component Development and Prototypes</b>	<b>0603807A - Medical Systems - Adv Dev</b>																<b>837</b>															
Event Name	FY 08				FY 09				FY 10				FY 11				FY 12				FY 13				FY 14				FY 15			
	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
Coliform Analyzer (MS-B)	MS B 																															
Environmental Sentinel Biomonitor (2nd QTR FY 09)					MS B 																											

**Schedule Detail (R4a Exhibit)**

**May 2009**

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>		PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>					PROJECT <b>837</b>	
<u>Schedule Detail</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>	<u>FY 2014</u>	<u>FY 2015</u>
Coliform Analyzer (MS-B)	3Q							
Environmental Sentinel Biomonitor (2nd QTR FY 09)		2Q						

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>		<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>A01</b>
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
A01 COMBAT SUPPORT HOSPITAL - MOBILE SURGICAL UNIT	5796				

**A. Mission Description and Budget Item Justification:** Not applicable for this item.

**Accomplishments/Planned Program:** Not applicable for this item.

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

**C. Acquisition Strategy** Not applicable for this item.

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>		<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>CS4</b>
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
CS4 MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)	6376	3987			10363

**A. Mission Description and Budget Item Justification:** Not applicable for this item.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Small Business Innovative Research/Small Business Technology Transfer Program	6376	112	
Congressional special interest in Medical systems initiatives		3875	
Total	6376	3987	

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

**C. Acquisition Strategy** Not applicable for this item.

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

**May 2009**

BUDGET ACTIVITY <b>4 - Advanced Component Development and Prototypes</b>		PE NUMBER AND TITLE <b>0603807A - Medical Systems - Adv Dev</b>			PROJECT <b>MD4</b>	
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost	
MD4 FUTURE MEDICAL SHELTER	1932				1932	

**A. Mission Description and Budget Item Justification:** Not applicable for this item.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
New Accomplishment	1932		
Total	1932		

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

**C. Acquisition Strategy** Not applicable for this item.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
<b>4 - Advanced Component Development and Prototypes</b>			<b>0603807A - Medical Systems - Adv Dev</b>								<b>MD4</b>	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
New R3 Line				1932							1932	
Subtotal:				1932							1932	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
New R3 Line												
Subtotal:												
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
<b>Project Total Cost:</b>				<b>1932</b>							<b>1932</b>	

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

**May 2009**

<b>BUDGET ACTIVITY</b> <b>4 - Advanced Component Development and Prototypes</b>		<b>PE NUMBER AND TITLE</b> <b>0603807A - Medical Systems - Adv Dev</b>			<b>PROJECT</b> <b>MD8</b>
COST (In Thousands)	FY 2008 Actual	FY 2009 Estimate	FY 2010 Estimate	Cost to Complete	Total Cost
MD8 ELECTROSOMOTIC PAIN THERAPY SYSTEM (CA)	1548				1548

**A. Mission Description and Budget Item Justification:** Not applicable for this item.

<b><u>Accomplishments/Planned Program:</u></b>	<u>FY 2008</u>	<u>FY 2009</u>	<u>FY 2010</u>
Congressional Special Interest	1548		
Total	1548		

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

**C. Acquisition Strategy** Not applicable for this item.

# ARMY RDT&E COST ANALYSIS (R3)

May 2009

BUDGET ACTIVITY			PE NUMBER AND TITLE								PROJECT	
4 - Advanced Component Development and Prototypes			0603807A - Medical Systems - Adv Dev								MD8	
I. Product Development	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
New R3 Line				1548							1548	
Subtotal:				1548							1548	
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
III. Test And Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 2008 Cost	FY 2008 Award Date	FY 2009 Cost	FY 2009 Award Date	FY 2010 Cost	FY 2010 Award Date	Cost To Complete	Total Cost	Target Value of Contract
Subtotal:												
<b>Project Total Cost:</b>				<b>1548</b>							<b>1548</b>	