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Exhibit R-2, RDT&E Budget Item Justification: PB 2014 Navy **DATE:** April 2013

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>
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COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
Total Program Element	25.948	32.118	14.880	9.458	-	9.458	9.643	10.225	10.394	10.011	Continuing	Continuing
0933: <i>Medical/Dental Equipment Dev</i>	9.234	14.018	14.880	9.458	-	9.458	9.643	10.225	10.394	10.011	Continuing	Continuing
9999: <i>Congressional Adds</i>	16.714	18.100	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	34.814

[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012

^{##} The FY 2014 OCO Request will be submitted at a later date

A. Mission Description and Budget Item Justification

The purpose of this budget item is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. There is a strong potential for dual use, technology transfer, and biotechnology firms/industry participation in the projects.

B. Program Change Summary (\$ in Millions)

	<u>FY 2012</u>	<u>FY 2013</u>	<u>FY 2014 Base</u>	<u>FY 2014 OCO</u>	<u>FY 2014 Total</u>
Previous President's Budget	33.034	12.707	9.471	-	9.471
Current President's Budget	32.118	14.880	9.458	-	9.458
Total Adjustments	-0.916	2.173	-0.013	-	-0.013
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-0.041	0.000			
• SBIR/STTR Transfer	-0.875	0.000			
• Rate/Misc Adjustments	0.000	2.173	-0.013	-	-0.013

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: 9999: *Congressional Adds*

Congressional Add: *Military Dental Research*

Congressional Add: *Wound Care Research (transferred from Defense Health Program)*

Congressional Add Subtotals for Project: 9999

FY 2012	FY 2013
5.100	-
13.000	-
18.100	0.000

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<u>Congressional Add Details (\$ in Millions, and Includes General Reductions)</u>		FY 2012	FY 2013
Congressional Add Totals for all Projects		18.100	0.000

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Navy										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: System Development & Demonstration (SDD)					R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development				PROJECT 0933: Medical/Dental Equipment Dev			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013 [#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
0933: Medical/Dental Equipment Dev	9.234	14.018	14.880	9.458	-	9.458	9.643	10.225	10.394	10.011	Continuing	Continuing
Quantity of RDT&E Articles	0	0	0	0		0	0	0	0	0		
# FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012												
## The FY 2014 OCO Request will be submitted at a later date												
A. Mission Description and Budget Item Justification												
The purpose of this budget item is to develop biomedical equipment and related techniques to reduce morbidity; to enhance the logistic feasibility of modern medical care for combat casualties; to sustain casualties for evacuation to fixed medical facilities for definitive care; and to ensure that personnel are medically qualified for military duty. Each work unit undertaken in this project has a military requirement. Efforts are justified based upon military payoff and cost benefit. There is a strong potential for dual use, technology transfer, and biotechnology firms/industry participation in the projects.												
B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)									FY 2012	FY 2013	FY 2014	
Title: Medical/Dental Equipment Dev									12.068	12.707	9.458	
									Articles: 0	0	0	
FY 2012 Accomplishments:												
Wound Management Program - Integrate efforts in wound closure, Hyperspectral Imaging, Heterotopic Ossification, and stem cell applications for wound repair. The system will provide improved diagnostic measures of wound healing.												
Monitoring, Oxygen Ventilation and External Suction (MOVES) System -Continued effort toward providing enhance capability for enhance control module & cardiovascular monitoring.												
Intranasal Carbon Dioxide for Headache and Trigeminal Muscle Pain - Continued efforts to provide an abortive migraine therapy with minimal side effects and high efficacy for use on deployment and in Military Treatment Facilities. Lead study data integrator identified to coordinate research sites.												
Attenuated Sporozoite Malaria Vaccine for Military Personnel - Continued augmented efforts with the ongoing clinical trial effort to test, for safety and efficacy, a militarily relevant malaria vaccine regimen utilizing a promising novel vaccine candidate.												
Impact of Marine Suicide on Family Survivors - Penn State will examine factors predicting resilience and well-being of Marine Corps families and determine needs addressable by intervention techniques.												

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
USMC Suicide Prevention Program Resiliency Study and Related Efforts - Initiate research leveraging the Marine Resiliency study, adding targeted studies of Marines that may be applicable to larger cohorts. Proposed aims include addition of assessments to include 12-month after deployment return to determine risk for chronic PTSD and potential factors for mitigation. Effort includes assessment of postvention efforts and psychological studies.			
Implementation of an Alternative Watchstanding Schedule on Navy Surface Combatants - Initiate study to analyze individualized fatigue-mitigated scheduling.			
Human Factors Support of OWL Tool - initiate development of systems-design tool in support of the Pulsar Informatics project in order to: coordinate fleet user survey; perform task analysis; assist GUI layout and design; collaborate on experimental design and submit IRB protocols; and generate technical reports.			
Intranasal Scopolamine - Initiate study for the prevention of motion sickness in dynamic military environments.			
Battalion Aid Station (BAS) Capabilities Study - Initiate study to conduct analysis on the current state of BAS configuration used by Marine Ground Combat Element (GCE) during garrison, contingency operations and support of Marine Air Combat Elements (ACE)			
Clinical Trials Site Expansion for Biomarkers - Biomarker study and clinical trials site expansion in support of Wound Management Program.			
Treatment Response Modeling for Crew Injuries Resulting from Weapons Attack - Completed refinement of model for medical chain requirements for evacuation patient outcomes. Determined probabilistic representation of mortality function and coordinated with software developer to ensure interoperability with the Office of Naval Research.			
SUBSCREEN Modification - The submarine duty psychological screening test, SUBSCREEN, required modification and validation for mixed gender use; this modification study will execute these functions.			
Biosurveillance Information Service (BioServ) - Develop a Biosurveillance Information Service (BioServ) to enable access to multiple data sets related to current and projected health risks enhancing force health protection and mission readiness at all levels.			
Rapid Blood Typing for Role II Units with Naval Medical Research Unit - San Antonio (NAMRU-SA) - Compare automated blood typing industry standard against proposed kit.			

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
Validation of Computerized Color Vision Tests for Use in Naval Aviation - Commence evaluation of new, more sensitive, instruments developed to detect and diagnose color vision deficiencies for potential use to screen candidates for color deficiencies that may compromise safety and operational performance in next generation military aviation platforms.			
Sterilucient Sterilizer - develop a portable, efficient sterilizer that operates off standard power supplies, has a low temperature process and a fast turn around time. Done in conjunction with MARCORSYSCOM			
Noise-Induced Hearing Loss: Administration of NAC and HPN-07-Clinical Trials - Advance the commercialization of NHPN-1010 by completing the toxicology, pharmacokinetic and animal efficacy and dose optimization studies.			
Synthetic Platelets in Swine Liver Injury Model - Develop an intravenous infusible nanoparticle product to promote hemostasis and survival following a liver injury in swine.			
Clinical Trials Site Expansion for Biomarkers - Biomarker study and clinical trials site expansion in support of Wound Management Program.			
Individualized Fatigue-Based Scheduling and Countermeasure System - Initial study is underway for development of a tool that predicts, prevents, detects, and mitigates periods of high risk associated with fatigue. Research leveraged is based upon an effort funded by the Office of Naval Research.			
FY 2013 Plans: Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Moving toward completing development of MOVES anesthesia module. This device is a pre-planned product improvement for FRSS deployment for MTFs, Medicine Clinics, Corpsman, and Navy or USMC Special Operations. Joint effort to result in Marine Corps procurement.			
Wound Management Program - Continued integration efforts in wound closure, Hyperspectral Imaging, Heterotopic Ossification, and stem cell applications for wound repair. The system will provide improved diagnostic measures of wound healing.			
SUBSCREEN Modification - This study will be completed and result in the required modification and validation of SUBSCREEN for mixed gender use.			
Intranasal Carbon Dioxide for Headache and Trigeminal Muscle Pain - Complete study supporting provision of an abortive migraine therapy with minimal side effects and high efficacy for use on deployment and in Military Treatment Facilities.			

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
Individualized Fatigue-Based Scheduling and Countermeasure System - Continue research supporting development of a tool that predicts, prevents, detects, and mitigates periods of high risk associated with fatigue. Coordinate with the Office of Naval Research to facilitate transition.				
USMC Suicide Prevention Program Resiliency Study and Related Efforts - Continue research leveraging the Marine Resiliency study and the execution of targeted studies of Marines. Address aims including addition of assessments to include 12-month after deployment return to determine risk for chronic PTSD and potential factors for mitigation. Effort includes assessment of postvention efforts and psychological studies.				
Joint Development Projects with MARCORSYSCOM Medical Acquisition - Continue Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement.				
Transition Projects from Force Health Protection Future Capability - Continue Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).				
Attenuated Sporozoite Malaria Vaccine for Military Personnel - Complete augmented efforts with the ongoing clinical trial effort to test, for safety and efficacy, a militarily relevant malaria vaccine regimen utilizing a promising novel vaccine candidate.				
Individualized Fatigue-Based Scheduling and Countermeasure System - Complete research supporting development of a tool that predicts, prevents, detects, and mitigates periods of high risk associated with fatigue. Periods of high individualized performance risk will be predicted and prevented by providing individual, specific, and fatigue optimized schedules and mitigation strategies.				
USMC Suicide Prevention Program Resiliency Study and Related Efforts - Complete research leveraging the Marine Resiliency study and the execution of targeted studies of Marines. Address aims including addition of assessments to include 12-month after deployment return to determine risk for chronic PTSD and potential factors for mitigation. Effort includes assessment of postvention efforts and psychological studies.				
Biosurveillance Information Service (BioServ) - Define decision rules for data sources to allow for dissemination of warning notifications.				
Rapid Blood Typing for Role II Units with Naval Medical Research Unit - San Antonio (NAMRU-SA) - Test proposed kit for rapid, reliable, and user-friendly field use.				

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013
Validation of Computerized Color Vision Tests for Use in Naval Aviation - Conduct a validation study to ensure key performance parameters are met.			
Foreign Directed Energy System Exploitation - Exploitation of foreign directed energy devices for bioeffects.			
FY 2014 Plans: USMC Suicide Prevention Program Resiliency Study and Related Efforts - Complete research leveraging the Marine Resiliency study and the execution of targeted studies of Marines.			
Attenuated Sporozoite Malaria Vaccine for Military Personnel - Continue ongoing clinical trial effort to test, for safety and efficacy, a militarily relevant malaria vaccine regimen utilizing a promising novel vaccine candidate.			
Biosurveillance Information Service (BioServ) - Conduct training and develop maintenance plan.			
Rapid Blood Typing for Role II Units with Naval Medical Research Unit - San Antonio (NAMRU-SA) - Apply for Clinical Laboratory Improvement Amendment waiver and Biological License Application. Pass Food & Drug Administration Inspection on manufacturing processes.			
Validation of Computerized Color Vision Tests for Use in Naval Aviation - Transition test meeting exit criteria of exhibiting a lower diagnostic error rate (less than the current 20% of color deficient candidates passing).			
Transition Projects from Force Health Protection Future Capability - Continue Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development program. Focus will be on transition of resuscitation agents, and mitigation of neurotrauma and post-traumatic stress.			
Title: Tactical Logistics Planning Tool		0.475	0.481
Articles:		0	0
FY 2012 Accomplishments: OCO: Discovery phase to identify the information technology structures and interface opportunities between TML+ and the Navy wargaming simulations has commenced. Implementation, testing, and refinement will also be conducted.			
FY 2013 Plans: OCO:			
			0.000

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)				FY 2012	FY 2013	FY 2014
A research tool that models patient flow from the point of injury through definitive care, and an analysis tool that supports OCO operational risk assessment, field medical services planning and systems analysis. Because it can handle larger amounts of data, TML+ provides the capability to model medical treatment facilities at all levels of care and their respective functional areas, the number and type of personnel, and the type, speed, and capacity of transportation assets. The plan is to continue to develop specific modeling capabilities in TML+ to support the development of OCO medical plans that optimize clinical outcomes for combat casualties using the minimum amount of manpower, materiel, and CASEVAC/Enroute care resources.						
Title: Combat Trauma Registry - Expeditionary Medical Encounter Database (CTR EMED) Articles:				0.875 0	0.892 0	0.000
FY 2012 Accomplishments: OCO: Commenced development of a tri-service expeditionary database that captures and codes clinical data (battle injury, non-battle injury, disease, and mental health encounters) to create a continuous running average of injury trends occurring in theater.						
FY 2013 Plans: OCO: Tri-service database of all battle injuries, non-battle injuries, disease, and mental health encounters that occur in deployed medical treatment facilities supporting OCO. The CTR EMED tracks each casualty, develops a detailed injury profile of the casualty's injuries and severities in near real-time. The tactical, operational, and casualty clinical data are forwarded to the intelligence, materiel developer and threat mitigation communities. Continue to maintain CTR EMED infrastructure necessary for supporting these OCO threat mitigation initiatives.						
Title: Validation of the Human Surrogate (HS) Prototype Articles:				0.240 0	0.400 0	0.000
FY 2012 Accomplishments: OCO: Began pre-testing of human surrogate equipment for biofidelic experimental response.						
FY 2013 Plans: OCO: Validation of the Human Surrogate (HS) Prototype will help determine the margin of safety of microwave counter Improvised Explosive Devices (IEDs) devices and munitions. The HS model, developed by Greenwave Scientific Inc., designed to be used to make accurate measurements of the specific absorption rate (SAR) of RF energy in the human body from Counter Radio-Controlled Electronic Warfare (CREW) devices. The absorption of radiofrequency (RF) by the human body is very complex. It is well known that even uniform RF exposures lead to non-uniform absorption in almost all human exposure situations. Current						

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B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)		FY 2012	FY 2013	FY 2014
methods to measure SAR in the human body are elegant and elaborate processes but they can only be carried out in the laboratory. These consist of open and closed human phantom shells filled with liquids that simulate the electrical properties of human tissue. To measure the uneven absorption of RF energy a small electric field probe is mechanically moved around inside the phantom shell during exposure.				
Continue work on the HS model and the evaluation of the accurate measurements of the specific absorption rate of radio frequent energy in the human body from Counter Radio-Controlled Electronic Warfare devices. Start developing some initial research studies looking at the long term use of the Counter Radio-Controlled Electronic Warfare devices.				
Title: Laser Field Testing Articles: FY 2012 Accomplishments: OCO Initiated Acoustic and Laser Field Test efforts to evaluate commercial-off-the-shelf and government-off-the-shelf non-lethal weapons technology complete to evaluate the effectiveness of a combined acoustic and laser device as a long-range hailing and warning device. FY 2013 Plans: OCO: Based on a 5th Fleet Urgent Requirement, an evaluation of various commercial-off-the-shelf (COTS) and government-off-the-shelf (GOTS) Non-Lethal Weapons (NLW) technology is required to determine the effectiveness of a combined Acoustic and Laser device as a long range NLW hailing and warning device. The bioeffects effort will support legal, policy and treating development for these NLW devices and future acquisition to deploy these types of systems in-theatre. Continue the laboratory and field testing of the effectiveness of a combined Acoustic and Laser device as a long range NLW hailing and warning device. Conduct additional field testing under operational conditions.		0.143 0	0.400 0	0.000
Title: Counter Directed Energy Bio-effects Articles: FY 2012 Accomplishments: Counter Directed Energy Bio-effects: Test chambers/facilities subjected to certification for testing of directed energy effects and methodologies for protection.		0.217 0	0.000	0.000
Accomplishments/Planned Programs Subtotals		14.018	14.880	9.458

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C. Other Program Funding Summary (\$ in Millions) N/A		
Remarks		
D. Acquisition Strategy The acquisition strategy for product lines and products in the Medical Development Program is designed and implemented consistent with the particular product and with the nature and size of the investment. The Medical Development Program operates with a Memorandum of Understanding with the Marine Corps Systems Command (Family of Field Medical Equipment) for co-development of products for procurement by the USMC. The acquisition strategy for these products involved direct partnership with the acquisition and procurement professionals at Marine Corps Systems Command. The program's major Product Areas in the Medical Development Program are: 1) Equipment 2) Pharmaceuticals/Biologics, and 3) Knowledge/Concepts. The primary Program Areas of Interest are in: 1) Expeditionary Medicine (Navy in Terrestrial, Maritime Surface, Submarine, & Aviation Operations and USMC in Expeditionary Operations) - in these areas the focus is on Levels I and II in Clinical Care Medicine; and 2) Products developed for battlefield treatment of Combat Casualties & Combat Trauma, focusing on delivery of Levels III and IV of care. For areas 1 and 2, there are two primary acquisition strategies. The first is to test and evaluate commercially-developed medical product candidates in managed trials for ultimate Food and Drug Administration (FDA) approval. Partnerships with commercial developers ensure that products of military interest are available for procurement across the DoD, Federal Government, and commercial market. During development, DoD end users are included in the process to the extent possible. The second strategy is to drive the development process with DoD program investments. This process involves developing in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding. Both strategies promote advanced preparation of procurement plans in line with the product availability. Major Medical Development programs falling in these categories are: MOVES and MOVES anesthesia module (Equipment), Dengue vaccine, and Infusible Hemostatic-Phase I Clinical Trials (Pharmaceuticals/Biologics). The Third Product Area (Knowledge/Concepts) is focused on the introduction of technologies, techniques, and procedures that alter medical practice and standards of care. These primarily require early involvement of the senior leadership of military medicine, in that the result of the program is modification of concepts of operations, policy, and/or doctrine. These are often much smaller; Medical Development Program examples include Navy/USMC Medical Planning Requirement Assessment and Crisis Action Planning Tool Transition. Programs such as System for Objective Decision-Making on Timing of Wound Closure involve both material and knowledge solutions.		
E. Performance Metrics Maintaining Scheduled Milestones/Demonstration Events for individualized project/product roadmap. Ensuring dependencies across multiple efforts are maintained on schedule and are primary metrics.		

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Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
P. Falciparum Malaria Vaccine for Military Personnel	MIPR	NMRC:Silver Spring, MD	0.700	3.774	Jun 2012	1.813	Dec 2012	0.000		-		0.000	0.000	6.287	
Wound Management Program (Hyperspectral Imaging/System for Objective Decision-Making on the Timing of Wound Closure/Hetrotopic Ossification	SS/FP	NMRC:Silver Spring, MD	1.036	0.164	Aug 2012	0.000		0.000		-		0.000	0.000	1.200	
MOVES System Reconfiguration	SS/FP	Thornhill Research, Inc:Toronto, Canada	1.000	0.677	Aug 2012	0.000		0.000		-		0.000	0.000	1.677	
Intranasal Carbon Dioxide for Headache	C/FFP	CAPNIA/McConnell Group:Rockville MD	0.250	0.000		1.130	Dec 2012	0.000		-		0.000	0.000	1.380	
USMC Resiliency Study II	SS/FP	HQ USMC:University of San Diego, CA	2.098	1.569	Jan 2012	2.400	Dec 2012	0.830	Dec 2013	-		0.830	Continuing	Continuing	Continuing
USMC Suicide Prevention Program - Marine Resiliency Study	SS/FP	HQ USMC:VA San Diego, CA	0.702	0.561	Apr 2012	0.510	Dec 2012	0.000		-		0.000	0.000	1.773	
Individualized Fatigue-Based Scheduling and Countermeasure System	SS/FP	Pulsar Informatics:Philadelphia, PA	1.348	1.348	Feb 2012	1.364	Dec 2012	0.000		-		0.000	0.000	4.060	
Sterilucent Sterilizer	C/FP	MARCORSYSCOM:Quantico, VA	0.500	0.075	Sep 2012	0.000		0.000		-		0.000	0.000	0.575	
Intranasal Scopolamine for the Prevention of Motion Sickness in Dynamic Military Environments	Allot	NAMRU-Dayton:Dayton, OH	0.250	0.395	Aug 2012	0.125	Dec 2012	0.000		-		0.000	0.000	0.770	
Malaria Vaccine/Clinical Testing Amendment: Radiation-Attenuated Whole	Allot	NMRC:Silver Spring, MD	0.700	0.000		0.189	Dec 2012	0.246	Dec 2013	-		0.246	0.000	1.135	

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Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Noise Induced Hearing Loss: Administration of NAC and HPN-07-Clinical Trials	SS/FP	Otologic, Pharma:Carlsbad, CA	0.000	0.689	Aug 2012	0.000		0.000		-		0.000	0.000	0.689	
Synthetic Platelets in Swine Liver Injury Model	SS/FP	Case Western University:Cleveland, OH	0.000	0.162	Aug 2012	0.000		0.000		-		0.000	0.000	0.162	
Battalion Aid Station Capabilities Study	Allot	NHRC:San Diego, CA	0.000	0.495	May 2012	0.000		0.000		-		0.000	0.000	0.495	
Biosurveillance Information Service (BioServ)	Allot	NAMRU-2:Pearl Harbor, HI	0.000	0.381	Sep 2012	0.125	Dec 2012	0.150	Jun 2014	-		0.150	0.000	0.656	
Implentation of an Alternative Watchstanding Schedule on USN Surface Combatants	MIPR	Naval Postgraduate School:Monterey, CA	0.000	0.000		0.112	Dec 2012	0.000		-		0.000	0.000	0.112	
Human Factors Support and Test of OWL Tool	Allot	NSMRL:Groton, CT	0.000	0.195	Aug 2012	0.215	Dec 2012	0.000		-		0.000	0.000	0.410	
TML+ Scenario Run/Fleet Forces	MIPR	NHRC:San Diego, CA	0.000	0.500	Jul 2012	0.000		0.000		-		0.000	0.000	0.500	
Plasma-Dry Blood Products-AFRIMS	MIPR	NMRDC:Ft. Detrick, MD	0.150	0.000		0.000		0.000		-		0.000	0.000	0.150	
Field Friendly Rapid Blood Typing Capabilities to Support Role II Units	Allot	NAMRU-SA:San Antonio, TX	0.000	0.240	Aug 2012	0.400	Dec 2012	0.385	Dec 2013	-		0.385	0.000	1.025	
Validation of Computerized Color Vision Tests for Use in Naval Aviation	Allot	NAMRU-Dayton:Dayton, OH	0.000	0.425	Jul 2012	0.375	Dec 2012	0.000		-		0.000	0.000	0.800	
Product Development	TBD	Various:Not Specific	0.000	0.000		3.949	Dec 2012	7.847	Dec 2013	-		7.847	0.000	11.796	
Medical/Dental Equipment Development	Allot	Various:Not Specific	0.300	1.950	Sep 2012	2.173	Dec 2012	0.000		-		0.000	0.000	4.423	
Test of Specialized Lighting to Improve	Allot	NSMRL:Groton, CT	0.000	0.010	Aug 2012	0.000		0.000		-		0.000	0.000	0.010	

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Navy													DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>							R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>				PROJECT 0933: <i>Medical/Dental Equipment Dev</i>				

Product Development (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Submariner Circadian Physiology															
Program Suport	C/FFP	NMRC:Silver Spring, MD	0.200	0.181	Sep 2012	0.000		0.000		-		0.000	0.000	0.381	
Evaluation of an Alternative Watchstanding Schedule fo the US Navy Surface Warfare Community	Allot	NSMRL:Groton, CT	0.000	0.227	Aug 2012	0.000		0.000		-		0.000	0.000	0.227	
Subtotal			9.234	14.018		14.880		9.458		0.000		9.458			

	All Prior Years	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	9.234	14.018	14.880	9.458	0.000	9.458			

Remarks

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Navy																							DATE: April 2013					
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: System Development & Demonstration (SDD)												R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development												PROJECT 0933: Medical/Dental Equipment Dev				
MALARIA	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
	Malaria Vaccine Research																											
	Adenovector Manufacturing																											
	Pre-Investigational New Drug and Toxicological Study				Milestone ▲																							
	Preparation of Materials for trials				Milestone ▲																							
	Clinical Trial								Milestone																			

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Navy																DATE: April 2013												
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: System Development & Demonstration (SDD)										R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development								PROJECT 0933: Medical/Dental Equipment Dev										
MIGRAINES	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Complete IRB Process				Milestone ▲																								
Complete Enrollment of 400 Subjects with Migraine at MTFs and VA facilities					Milestone																							
Analyze Data and Submit Findings to FDA								Milestone ▲																				
FDA Review and Follow-On								Milestone ▲																				
2014DON - 0604771N - 0933																												

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Navy																							DATE: April 2013					
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: System Development & Demonstration (SDD)												R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development												PROJECT 0933: Medical/Dental Equipment Dev				
USMC SUICIDE	FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
psychological Autopsy Study- Full Report with Conclusions and Risk Checklist	Milestone																											
Impact of USMC Suicide on Family Survivors- Recommendations for Postvention Efforts					Milestone																							
Marine Resiliency									Milestone																			
2014DON - 0604771N - 0933																												

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PE 0604771N: *Medical Development*
Navy

R-1 Line #125

R-1 ITEM NOMENCLATURE

PE 0604771N: Medical Development

0933: Medical/Dental Equipment Dev

[illegible]

2014DON - 0604771N - 0933

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Exhibit R-4, RDT&E Schedule Profile: PB 2014 Navy																								DATE: April 2013					
APPROPRIATION/BUDGET ACTIVITY 1319: Research, Development, Test & Evaluation, Navy BA 5: System Development & Demonstration (SDD)												R-1 ITEM NOMENCLATURE PE 0604771N: Medical Development								PROJECT 0933: Medical/Dental Equipment Dev									
Force Health Protection Transition Projects		FY 2012				FY 2013				FY 2014				FY 2015				FY 2016				FY 2017				FY 2018			
		1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Continue Development									Milestone																				

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Exhibit R-4A, RDT&E Schedule Details: PB 2014 Navy			DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>	

Schedule Details

Events by Sub Project	Start		End	
	Quarter	Year	Quarter	Year
<i>MALARIA</i>				
Malaria Vaccine Research:	1	2012	4	2012
Adenovector Manufacturing:	1	2012	4	2012
Pre-Investigational New Drug and Toxicological Study:	1	2013	1	2013
Preparation of Materials for trials:	1	2013	1	2013
Clinical Trial: Schedule Detail	2	2013	4	2013
<i>MIGRAINES</i>				
Complete IRB Process:	4	2012	4	2012
Complete Enrollment of 400 Subjects with Migraine at MTFs and VA facilities: Schedule Detail	1	2013	3	2013
Analyze Data and Submit Findings to FDA: Schedule Detail	4	2013	4	2013
FDA Review and Follow-On: Schedule Detail	4	2013	4	2013
<i>USMC SUICIDE</i>				
psycological Autopsy Study- Full Report with Conclusions and Risk Checklist: Schedule Detail	1	2012	4	2012
Impact of USMC Suicide on Family Survivors- Recommendations for Postvention Efforts: Schedule Detail	1	2013	4	2013
Marine Resiliency: Schedule Detail	1	2014	4	2014
<i>INDIVIDUALIZED FATIGUE</i>				
Develop Sub Community Schedule: Schedule Detail	1	2012	4	2012
Test Schedule: Schedule Detail	1	2013	4	2013
<i>Force Health Protection Transition Projects</i>				
Continue Development: Schedule Detail	4	2013	1	2014

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Navy										DATE: April 2013		
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>					R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>				PROJECT 9999: <i>Congressional Adds</i>			
COST (\$ in Millions)	All Prior Years	FY 2012	FY 2013[#]	FY 2014 Base	FY 2014 OCO ^{##}	FY 2014 Total	FY 2015	FY 2016	FY 2017	FY 2018	Cost To Complete	Total Cost
9999: <i>Congressional Adds</i>	16.714	18.100	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	34.814
Quantity of RDT&E Articles	0	0	0	0		0	0	0	0	0		
[#] FY 2013 Program is from the FY 2013 President's Budget, submitted February 2012 ^{##} The FY 2014 OCO Request will be submitted at a later date												
<u>A. Mission Description and Budget Item Justification</u>												
Congressional Adds												
<u>B. Accomplishments/Planned Programs (\$ in Millions)</u>								FY 2012	FY 2013			
<i>Congressional Add:</i> Military Dental Research								5.100	-			
<i>FY 2012 Accomplishments:</i> All Navy Military Dental Research projects are underway. FY12 research efforts include a number of continuation projects from FY11. These efforts include the following accomplishments: Evaluation of Incidence and Treatment of Dental Emergencies in Deployed Personnel; Third Molar Related Dental Emergency and Extractions in Deployed Personnel; Design /Fabrication of Rapid Prototype Titanium Implement for Head /Neck Reconstruction.												
<i>Congressional Add:</i> Wound Care Research (transferred from Defense Health Program)								13.000	-			
<i>FY 2012 Accomplishments:</i> The Wound Care Research Program is a comprehensive effort which continues to develop novel diagnostics and treatments to enhance the care of the wounded warfighter. The program utilizes cutting edge molecular assays and advanced computational biology to develop a device to predict the outcome of wounds. The development of novel treatments for wounds is based on the use of cells and factors to improve wound healing.												
Congressional Adds Subtotals								18.100	0.000			
<u>C. Other Program Funding Summary (\$ in Millions)</u>												
N/A												
<u>Remarks</u>												
<u>D. Acquisition Strategy</u>												
N/A												

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Exhibit R-2A, RDT&E Project Justification: PB 2014 Navy		DATE: April 2013
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 9999: <i>Congressional Adds</i>

E. Performance Metrics

Not required for Congressional adds.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2014 Navy												DATE: April 2013			
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>System Development & Demonstration (SDD)</i>						R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>				PROJECT 9999: <i>Congressional Adds</i>					

Test and Evaluation (\$ in Millions)				FY 2012		FY 2013		FY 2014 Base		FY 2014 OCO		FY 2014 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	All Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Congressional Add	C/BA	Not Specified:Not Specified	16.714	18.100	Jan 2012	0.000		0.000		-		0.000	0.000	34.814	
Subtotal			16.714	18.100		0.000		0.000		0.000		0.000	0.000	34.814	

	All Prior Years	FY 2012	FY 2013	FY 2014 Base	FY 2014 OCO	FY 2014 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	16.714	18.100	0.000	0.000	0.000	0.000	0.000	34.814	

Remarks