

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>
---	---

COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
Total Program Element	54.932	12.637	12.984	1.950	14.934	12.902	9.768	10.036	10.582	Continuing	Continuing
0933: <i>Medical/Dental Equipment Dev</i>	8.087	12.637	12.984	1.950	14.934	12.902	9.768	10.036	10.582	Continuing	Continuing
9999: <i>Congressional Adds</i>	46.845	-	-	-	-	-	-	-	-	0.000	46.845

A. Mission Description and Budget Item Justification

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. Program Change Summary (\$ in Millions)

	<u>FY 2010</u>	<u>FY 2011</u>	<u>FY 2012 Base</u>	<u>FY 2012 OCO</u>	<u>FY 2012 Total</u>
Previous President's Budget	56.692	12.337	14.054	-	14.054
Current President's Budget	54.932	12.637	12.984	1.950	14.934
Total Adjustments	-1.760	0.300	-1.070	1.950	0.880
• Congressional General Reductions		-			
• Congressional Directed Reductions		-			
• Congressional Rescissions	-	-			
• Congressional Adds		-			
• Congressional Directed Transfers		-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-1.758	-			
• Program Adjustments	-	0.300	-0.475	1.950	1.475
• Rate/Misc Adjustments	-	-	-0.595	-	-0.595
• Congressional General Reductions Adjustments	-0.002	-	-	-	-

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

Project: 9999: *Congressional Adds*

Congressional Add: *Biocidal Wound Dressings*

Congressional Add: *Deployment Health and Chronic Disease Surveillance*

Congressional Add: *Integrated Psycho-Social Health Care Demonstration Program*

	FY 2010	FY 2011
	1.195	-
	0.797	-
	0.996	-

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY	R-1 ITEM NOMENCLATURE
1319: <i>Research, Development, Test & Evaluation, Navy</i>	PE 0604771N: <i>Medical Development</i>
BA 5: <i>Development & Demonstration (SDD)</i>	

Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2010	FY 2011
Congressional Add: <i>Management of Lung Injury by Micronutrients</i>	1.195	-
Congressional Add: <i>Multivalent Dengue Vaccine Program</i>	1.275	-
Congressional Add: <i>National Functional Geonomics Center Colloborating Site</i>	3.187	-
Congressional Add: <i>Simplified Orthopedic Surgery</i>	4.222	-
Congressional Add: <i>Wound Care Research (transferred from Defense Health Program)</i>	12.946	-
Congressional Add: <i>Military Dental Research</i>	5.975	-
Congressional Add: <i>Advanced Molecular Medicine Initiative</i>	0.797	-
Congressional Add: <i>On-Demand Custom Body Implants/Prosthesis For Inju</i>	1.593	-
Congressional Add: <i>Hampton University Cancer Treatment Initiative</i>	3.983	-
Congressional Add: <i>Mobile Oxygen, Venilation & External Suction (Mo</i>	2.709	-
Congressional Add: <i>US Navy Pandamic Influenza Vaccine Program</i>	1.593	-
Congressional Add: <i>Composite Tissue Transplanation for Combat Wounded</i>	1.992	-
Congressional Add: <i>US Navy Cancer Vaccine Program</i>	2.390	-
Congressional Add Subtotals for Project: 9999	46.845	-
Congressional Add Totals for all Projects	46.845	-

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>
---	---	---

COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
0933: <i>Medical/Dental Equipment Dev</i>	8.087	12.637	12.984	1.950	14.934	12.902	9.768	10.036	10.582	Continuing	Continuing
Quantity of RDT&E Articles	0	0	0	0	0	0	0	0	0		

A. Mission Description and Budget Item Justification

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 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
Title: Medical/Dental Equipment Dev	8.087	12.337	12.984	1.950	14.934
Articles:	0	0	0	0	0
FY 2010 Accomplishments:					
- System for Objective Decision-Making on the Timing of Wound Closure - Continuing development of wound evaluation methods that integrate current standards with genetic expression profiles unique to wound healing. Identified commercial partners for diagnostic kit development. Focus is on development of test kit available for use in Military Treatment Facilities. Discussions with potential manufacturer of "dipstick" assay for a rapid, disposable, and diagnostic device.					
- Hyperspectral Imaging of Tissue Perfusion and Oxygenation in Extremity Wounds - Initiate development of an integrated spectroscopic imaging system to provide accurate assessment of tissue perfusion and oxygenation. The system will provide improved diagnostic measures of wound healing.					
- Heterotopic Ossification (HO) Incidence - Continued research on incidence and predisposing factors (e.g., combat polytrauma, Traumatic Brain Injury) of HO in patients based on a molecular profile, clinical indicators, and patient history. Continued investigation of the effects of psychoactive drugs on progenitor cell differentiation toward osteoblasts.					
- Treatment Response Modeling for Crew Injuries Resulting from Weapons Attack - Continued refinement of model for medical chain requirements for evacuation patient outcomes. Continued determination of the probabilistic representation of a mortality function, to be used with other stochastic models. Coordinated with software wrapper developer to ensure interoperability.					

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
<ul style="list-style-type: none"> - USMC Tourniquet Evaluation and Downselect - Model selection conducted in collaboration with Defense Medical Standardization Board, Army, and Air Force representatives. Joint effort with the Marine Corps to evaluate tourniquet performance in arresting bleeding and limb salvage in field injury scenarios. - Detection of Intracranial Hematoma - Refined field performance characteristics of a portable near infrared based mobile imaging device (Infrascanner) to detect brain hematoma at the site of injury. Device will be deployed in a joint effort with the Marine Corps. - Clinical Evaluation of a Vaxfectin TM - Formulated Tetravalent Dengue DNA Vaccine (VTDDV) - Progress on clinical investigations trials on four serotypes. - Establishing a 3D Craniofacial Image Protocol and Pre-Injury Database - Completed development of the database structure of 3D soft tissue and hard tissue pre-traumatic images of pre-deployed personnel. Finalizing efforts in management, transfer, and diagnostic use of images. Focused on data acquisition and transfer at Marine Corps clinics. - Monitoring, Oxygen Ventilation and External Suction (MOVES) System - Completed Phase I reconfiguration of MOVES to reduce weight and cost for subsequent production runs. Incorporate joint service requirements. Evaluating redesign features based on lessons-learned from MOVES field evaluations. Initiated TEMP development in collaboration with USMC. Initiated discussions on commercialization efforts. - Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Continued 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. - Intranasal Carbon Dioxide for Headache and Trigeminal Muscle Pain - Developing final protocol procedure for FDA Phase III clinical trials. Determined study sites and anticipated patient throughput. Initiate efforts to provide clinical guidance on abortive migraine therapy with minimal side effects and high efficacy for use on deployment and in Military Treatment Facilities. - Vasoactivity-Attenuated (VA) HBOC FY10 Initiative Toxicology Studies - Initiated large animal studies evaluating safety and effectiveness of VA Hemoglobin-based oxygen carriers for treatment, for severe hemorrhagic shock. - Spray-Dried Pooled Plasma - Initiated efforts to establish a second GMP capability. Developed preliminary FDA regulatory compliance plan. in a joint effort with the Office of Naval Research, USMC, and US Army. - Hemostatic Agent Evaluation in a Severe Vascular Hemorrhage or Liver Injury Model - Initiated testing a nano-particle based hemostatic dressing capable of controlling and arresting severe bleeding to decrease combat casualties. Initial results indicate that the liver-crush model in large animals may be inadequate to fully evaluate 					

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)

	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
<p>the effects of the dressing on severe internal organ injury. Effort is performed in conjunction with a product developed by the Office of Naval Research.</p> <ul style="list-style-type: none"> - Perfluorocarbons for Non-Recompressive Decompression - Continued tests of intravenous perfluorocarbons for adjunctive decompression sickness and arterial gas embolism therapy. The effort focused on large animal trials targeting FDA approval. The effort has continued on schedule despite delays in small animal model partner performance. This is a joint effort with ONR and NAVSEA. - Mitigation of Traumatic Brain Injury with Novel Pad Inserts - Initiated effort to manufacture improved protection provided by helmets through a new nanomaterial helmet insert that will absorb shock, impact, and vibration. Preliminary data are being assembled to develop major test plan. Initial prototype of insert set will be produced for human factors evaluation. - Phase I Clinical Trials for FDA approval of an Infusible Hemostatic Agent - Completed evaluation of one of two candidate agents in preclinical trials. Preparing plans for Phase I Safety Trials of the infusible hemostatic agent selected from pre-clinical tests. The agent is designed for applications to non-compressible injuries. Transition to US Army Medical Materials Development Agency for Phase II. - Attenuated Sporozoite Malaria Vaccine for Military Personnel - Augmented ongoing clinical trial effort to test, for safety and efficacy, a militarily relevant malaria vaccine regimen utilizing a promising novel vaccine candidate. Joint Development Projects with MARCORSYSCOM Medical Acquisition - Initiated Joint Development Testing and Evaluation program for medical products and equipment. <p>FY 2011 Plans:</p> <ul style="list-style-type: none"> - 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 - Initiate field testing and airworthiness testing for device. Continue configuration management of MOVES anesthesia module. Joint effort developed system to be procured by the Marine Corps. - Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Continue 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. - Intranasal Carbon Dioxide for Headache and Trigeminal Muscle Pain - Continue efforts to provide an abortive migraine therapy with minimal side effects and high efficacy for use on deployment and in Military Treatment Facilities. 					

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy	DATE: February 2011
--	----------------------------

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>
---	---	---

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
---	---------	---------	--------------	-------------	---------------

- Mitigation of Traumatic Brain Injury with Novel Pad Inserts - Continue effort to improve protection provided by helmets through a new helmet insert that will absorb shock, impact, and vibration.

- 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.

- Joint Development Projects with MARCORSSYSCOM 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 - Initiate 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).

- USMC Participation in the National Institute of mental Health (NIMH) Suicide Study - Provide annual report on risks and protective factors associated with increased suicides among Marines, while supporting the development of evidence-based prevention, assessment, and treatment services. Assessment and reporting will be in accordance with MOU developed with Department of the Army.

FY 2012 Base Plans:

- Mobile Oxygen Ventilation and External Suction (MOVES) Anesthesia - Complete 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.

- 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.

- 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.

- Joint Development Projects with MARCORSSYSCOM Medical Acquisition - Initiate Joint Development Testing and Evaluation program for medical products and equipment. Finalize development for USMC Procurement.

- Transition Projects from Force Health Protection Future Capability - Initiate Development, Testing, and Evaluation program for transition products from the Office of Naval Research 6.3 Advanced Development

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total
<p>program. Focus will be on transition of novel hemostatic agents (e.g. infusible hemostatics and field/first responder devices).</p> <p>FY 2012 OCO Plans:</p> <ul style="list-style-type: none"> - Determining and optimizing medical resource requirements for expeditionary medical units - An expeditionary medical modeling and simulation tool (the Theater Medical Logistics Planning Tool (TML+)) will be configured to project and optimize medical resource requirements. Resource projection capability will be developed for Tactical Combat Casualty Care and rhesus surgery. - Expeditionary Medical encounter Database (CTR EMED) - This project will capture expeditionary tactical and medical injury and illness data and map those data to long-term casualty clinical, rehabilitative and quality of life outcome data. This will have a long-term Force Health Protection benefit in the development of more effective body armor and protective gear. - Foreign Directed Energy System Exploitation - This project will examine the exploitation of foreign directed energy devices for bioeffects countermeasure development. This will provide enhanced methodology for Force Health Protection against foreign directed energy devices. 					
<p>Title: Combined Maritime Acoustic Device and Optical (Laser) Field Test</p> <p align="right">Articles:</p> <p>FY 2011 Plans:</p> <ul style="list-style-type: none"> - Combined Maritime Acoustic Device and Optical (Laser) Field Test - Based on a 5th Fleet 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 future acquisition to deploy these types of systems in-theater will be determined by the Armed Services based on this evaluation. 	-	0.300 0	-	-	-
Accomplishments/Planned Programs Subtotals	8.087	12.637	12.984	1.950	14.934

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

The acquisition strategy for product lines and products in the Medical Development Program designed and implemented consistent with the particular product and with the nature and size of the investment.

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>
<p>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), 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.</p> <p>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.</p> <p>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), and Dengue Vaccine and Infusible Hemostatic-Phase I Clinical Trials (Pharmaceuticals/Biologics).</p> <p>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 modifications 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.</p> <p>Programs such as System for Objective Decision-Making on Timing of Wound Closure involve both material and knowledge solutions.</p> <p>E. Performance Metrics</p> <p>Maintaining Scheduled Milestones/Demonstration Events for individualized project/product roadmap. Ensuring dependencies across multiple efforts are primary metrics.</p>		

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>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 2011		FY 2012 Base		FY 2012 OCO		FY 2012 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Total Prior Years Cost	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Mobile Anesthesia Delivery Module (MADM) Beta Prototype Development	SS/FP	Thornhill Research, Inc. Toronto:Canada	1.769	-		-		-		-	0.000	1.769	
MADM BP Animal Test	SS/FP	Thornhill Research, Inc. Toronto:Canada	0.983	-		-		-		-	0.000	0.983	
MADM Human Protocol Development	SS/FP	Thornhill Research, Inc. Toronto:Canada	0.983	-		-		-		-	0.000	0.983	
MADM	SS/FP	Thornhill Research, Inc. Toronto:Canada	1.700	3.389	Jun 2011	-		-		-	0.000	5.089	
SLC Cube and Weight Reduction of MOVES	SS/FP	Thornhill Research, Inc. Toronto:Canada	1.900	-		-		-		-	0.000	1.900	
Product Development	SS/FP	Various:Not Specified	0.752	9.248	Jun 2011	12.984	Oct 2011	-		12.984	Continuing	Continuing	Continuing
Medical/Dental Equipment Development	SS/FP	Various:Not Specified	-	-		-		1.950	Jul 2012	1.950	0.000	1.950	
Subtotal			8.087	12.637		12.984		1.950		14.934			

Remarks

1,2,3. MADM - Beta Prototype,BP Animal Test; Human Protocol Development:

This is being executed as partial funding of a new contract between RDECOM Natick, MA and Thornhill Research, Inc. The total contract value is approximately \$4,100K with the project jointly funded by the Navy (\$1.769K) and the USMC for a POP from 01 APR 2010 through 31 MAY 2011. These figures are based on a best breakout of the contribution from Project 0933 for all contracted efforts exceeding \$1,000K. The first two proofs of concepts (under N00244-07-C-1531) and the breadboard (under W911QY-08-C-0116) are already in progress and on their way to completion. Current efforts are in the design of the Alpha which is under contract W911QY-08-C-0116 option year. Testing on MADM will begin on animals in March. Next two phases of MADM will be focused on developing the Beta prototype and testing it on animals (base year), followed by building 10 units, verification and validation, environmental, EMC, and vibration testing, and human testing. POP for base year is 12 months which extends to 24 if the option is exercised.

4,5,6. MADM; SLC-Cube and Weight Reduction of MOVES; Product Development:

MADM is being executed as partial funding of a new contract between RDECOM Natick, MA and Thornhill Research, Inc. The total contract value is approximately \$4,100K with the project jointly funded by the Navy and the USMC for a POP from 01 APR 2010 through 31 MAY 2011. These figures are based on a best breakout of the contribution from Project 0933 for all contracted efforts exceeding \$1,000K. The first two proofs of concepts (under N00244-07-C-1531) and the breadboard (under W911QY-08-C-0116) are already in progress and on their way to completion. Current efforts are in the design of the Alpha which is under contract W911QY-08-C-0116 option year. It is anticipated that MARCORSYSCOM will assume funding of this effort in BY2 under the existing MOA.

The SLC program incorporates redesign and reconfiguration efforts to enhance the USMC en route care device capability set. The core program effort is supplemented by a congressional add that augments final RDT&E efforts of MOVES and configuration and redesign of SLC.

Product Development incorporates numerous small efforts within major product lines to address the Navy Surgeon General's priorities. These efforts include:

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 0933: <i>Medical/Dental Equipment Dev</i>

--	--	--

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>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
Proj 0933				
0933 - SLC - Fabricate Alpha Prototypes	3	2010	4	2010
0933 - SLC Bench Test Prototypes	1	2011	1	2011
0933 - SLC Develop Test Plans	1	2011	2	2011
0933 - SLC Fabricate Beta Prototypes	3	2011	3	2011
0933 - SLC Verification and Validation Testing	4	2011	2	2012
0933 - MADM - Critical Design Review	1	2010	4	2010
0933 - MADM - Animal Studies	1	2010	4	2011
0933 - MADM - Human Studies	1	2010	4	2012
0933 - MADM - Final Report	4	2012	4	2012

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 9999: <i>Congressional Adds</i>
---	---	---

COST (\$ in Millions)	FY 2010	FY 2011	FY 2012 Base	FY 2012 OCO	FY 2012 Total	FY 2013	FY 2014	FY 2015	FY 2016	Cost To Complete	Total Cost
9999: <i>Congressional Adds</i>	46.845	-	-	-	-	-	-	-	-	0.000	46.845
Quantity of RDT&E Articles	0	0	0	0	0	0	0	0	0		

A. Mission Description and Budget Item Justification

Congressional Adds

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2010	FY 2011
Congressional Add: Biocidal Wound Dressings	1.195	-
FY 2010 Accomplishments: This project will consist of testing and evaluation of wound dressings, which may remove more than 99.999% of bacteria, fungi and viruses passing through their media.		
Congressional Add: Deployment Health and Chronic Disease Surveillance	0.797	-
FY 2010 Accomplishments: This project will demonstrate and evaluate patient encounter points in the Arlington Health Clinics and provide lessons learned for health care record surveillance to the Department of Defense as a demonstration project. This demonstration will leverage civilian operational clinical settings in Northern Virginia and then evaluated for deployment applicability within the DoD.		
Congressional Add: Integrated Psycho-Social Health Care Demonstration Program	0.996	-
FY 2010 Accomplishments: This project proposes to enhance healthcare for US service members and their families, and to proactively address their unique psychological healthcare needs through the use of industry-leading targeted population management models. It will target a pilot population of DoD beneficiaries within a designated Military Treatment Facility area.		
Congressional Add: Management of Lung Injury by Micronutrients	1.195	-
FY 2010 Accomplishments: Continuation of pilot project that defined oxidative damage and inflammation in lung injury in military recruits and made a preliminary assessment of the effects of antioxidant micronutrient supplementation. The prospective, randomized, double blind, placebo-controlled study will evaluate impact on respiratory disease, military readiness and quality of life as well as laboratory data including antioxidant levels, markers of oxidative damage and inflammation.		
Congressional Add: Multivalent Dengue Vaccine Program	1.275	-
FY 2010 Accomplishments: Continued work to manufacture the two vaccine mixture under Good Manufacturing Processes (GMP) conditions for a Phase I clinical investigation; execution of the Phase I clinical		

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy		DATE: February 2011
APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 9999: <i>Congressional Adds</i>
B. Accomplishments/Planned Programs (\$ in Millions)	FY 2010	FY 2011
trial; and develop and test a single vaccine candidate that will produce neutralizing antibodies against all four serotypes in vaccinated animals.		
Congressional Add: National Functional Geonomics Center Colloborating Site	3.187	-
FY 2010 Accomplishments: This project will establish the Penn State Center for Pharmacogenetics which will create a repository of samples from every cancer patient that visits Penn State.		
Congressional Add: Simplified Orthopedic Surgery	4.222	-
FY 2010 Accomplishments: This project will further develop a computer-aided system that simplifies complex orthopedic surgical procedures by enabling them to be performed more accurately and quickly without using cumbersome and expensive mechanical jigs.		
Congressional Add: Wound Care Research (transferred from Defense Health Program)	12.946	-
FY 2010 Accomplishments: This project will support research for the advancement of deep tissue and surface wound care.		
Congressional Add: Military Dental Research	5.975	-
FY 2010 Accomplishments: Develop Antimicrobial Nanoemulsions to Prevent Infections in the Field. Evaluate the Incidence and Treatment Required for Dental Emergencies Occurring in Deployed Military Personnel. Conduct critical research in development of Antimicrobial Resin.		
Congressional Add: Advanced Molecular Medicine Initiative	0.797	-
FY 2010 Accomplishments: Continued research to improve cancer therapy primarily through improved understanding of cancer cell targeting with a focus on radiation therapy and in addition use of pioneering efforts of these investigators in science of radiation resistance to improve radiation resistance for potential casualties.		
Congressional Add: On-Demand Custom Body Implants/Prosthesis For Inju	1.593	-
FY 2010 Accomplishments: Continue testing and evaluation of Phase I efforts to develop manufacturing methods and materials necessary for rapid prototyping and delivery of prostheses. Apply state-of-the-art CAD/CAM procedures to prosthesis manufacturing technology.		
Congressional Add: Hampton University Cancer Treatment Initiative	3.983	-
FY 2010 Accomplishments: R&D efforts in continued support of continued progress in advanced technologies for diagnosis and treatment of cancer. Particular emphasis is placed on military and military veterans.		
Congressional Add: Mobile Oxygen, Venilation & External Suction (Mo	2.709	-

UNCLASSIFIED

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2012 Navy **DATE:** February 2011

APPROPRIATION/BUDGET ACTIVITY 1319: <i>Research, Development, Test & Evaluation, Navy</i> BA 5: <i>Development & Demonstration (SDD)</i>	R-1 ITEM NOMENCLATURE PE 0604771N: <i>Medical Development</i>	PROJECT 9999: <i>Congressional Adds</i>
---	---	---

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2010	FY 2011
<i>FY 2010 Accomplishments:</i> Continued reconfiguration of Low Rate Initial Production (LRIP) units Monitoring, Oxygen Ventilation and External Suction System (MOVES) human factors, weight, cube and cost. Reconfiguration of MOVES is specifically targeted to reduce weight and cost. Incorporate requirements from other services into LRIP units as part of the planned next generation research and development spiral. Configuration will be based on feedback from the warfighter and joint requirements for en-route care.		
<i>Congressional Add:</i> US Navy Pandemic Influenza Vaccine Program	1.593	-
<i>FY 2010 Accomplishments:</i> Initiated research to develop safe and effective pandemic influenza vaccines. Develop strategies to assure and protect the health of military personnel with these vaccines.		
<i>Congressional Add:</i> Composite Tissue Transplantation for Combat Wounded	1.992	-
<i>FY 2010 Accomplishments:</i> The FY10 funds will be used to conduct clinical trials for hand transplants. Identified and prepared candidate recipient for transplant. Awaiting compatible donor. All preparation works has continued during this phase. These funds are executed through an existing cooperative agreement through the National Business Center to Emory University.		
<i>Congressional Add:</i> US Navy Cancer Vaccine Program	2.390	-
<i>FY 2010 Accomplishments:</i> Continue development of a novel prostate cancer vaccine developed by Oncbiomune, LLC and support the development of an IND submission needed for FDA approval. Continue the Phase IA/B clinical trial to be carried out at the VA San Diego Healthcare System, located in San Diego, CA. US military veterans who have received previous treatment (surgery, radiation or radioactive seed implants) and now have a rising PSA are study participants.		
Congressional Adds Subtotals	46.845	-

C. Other Program Funding Summary (\$ in Millions)

N/A

D. Acquisition Strategy

N/A

E. Performance Metrics

Congressional Adds