Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Navy

Date: February 2018

**Appropriation/Budget Activity** 

R-1 Program Element (Number/Name)

1319: Research, Development, Test & Evaluation, Navy I BA 5: System

PE 0604771N I Medical Development

Development & Demonstration (SDD)

COST (\$ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
Total Program Element	139.490	24.510	9.353	8.095	-	8.095	8.214	9.067	9.291	9.520	Continuing	Continuing
0000: <i>UNDIST</i>	0.000	6.208	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	6.208
0933: Medical/Dental Equipment Dev	22.664	2.812	9.353	8.095	-	8.095	8.214	9.067	9.291	9.520	Continuing	Continuing
2896: Military Dental Research	0.000	0.015	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.015
9999: Congressional Adds	116.826	15.475	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	132.301

## A. Mission Description and Budget Item Justification

The purpose of this program 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 firm/industry participation in the projects.

B. Program Change Summary (\$ in Millions)	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total
Previous President's Budget	9.221	9.353	9.613	-	9.613
Current President's Budget	24.510	9.353	8.095	-	8.095
Total Adjustments	15.289	0.000	-1.518	-	-1.518
Congressional General Reductions	-	-			
Congressional Directed Reductions	-	-			
Congressional Rescissions	-	-			
Congressional Adds	-	-			
Congressional Directed Transfers	-	-			
Reprogrammings	-	-			
SBIR/STTR Transfer	-0.710	0.000			
Program Adjustments	-0.001	0.000	-1.160	-	-1.160
Rate/Misc Adjustments	0.000	0.000	-0.358	-	-0.358
Congressional Add Adjustments	16.000	-	-	-	-

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

Project: 9999: Congressional Adds

Congressional Add: Military Dental Research

FY 2018
0.000

PE 0604771N: Medical Development

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R-1 Line #153

Navy

Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Navy		Date: February 2018
	R-1 Program Element (Number/Name)	
1319: Research, Development, Test & Evaluation, Navy I BA 5: System	PE 0604771N I Medical Development	
Development & Demonstration (SDD)		

Congressional Add Details (\$ in Millions, and Includes General Reductions)	FY 2017	FY 2018
Congressional Add: Wound Care Research (transferred from Defense Health Program)	9.672	0.000
Congressional Add Subtotals for Project: 9999	15.475	0.000
Congressional Add Totals for all Projects	15.475	0.000

# **Change Summary Explanation**

The funding decrease in FY19 reflects a slower development of projects.

PE 0604771N: *Medical Development* Navy

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Exhibit R-2A, RDT&E Project Justification: PB 2019 Navy										Date: February 2018		
Appropriation/Budget Activity 1319 / 5							<b>t (Number</b> / al Developri	Project (No	Number/Name) IDIST			
COST (\$ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
0000: UNDIST	0.000	6.208	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	6.208
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-		

### Note

The FY 17 funding reflected in this project is erroneous due to a database error. This funding should be reflected in Project 0933.

### A. Mission Description and Budget Item Justification

The purpose of this program 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 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total
Title: Medical/Dental Equipment Development	6.208	0.000	0.000	0.000	0.000
Articles	: -	-	-	-	-
<b>FY 2018 Plans:</b> N/A					
FY 2019 Base Plans: N/A					
FY 2019 OCO Plans: N/A					
FY 2018 to FY 2019 Increase/Decrease Statement: N/A					
Accomplishments/Planned Programs Subtotals	6.208	0.000	0.000	0.000	0.000

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

N/A

Navy

Remarks

PE 0604771N: Medical Development

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Exhibit R-2A, RDT&E Project Justification: PB 2019 Navy		Date: February 2018	
	,	, ,	umber/Name)
1319 / 5	PE 0604771N I Medical Development	0000 <i>I UNI</i>	DIST

### D. Acquisition Strategy

The major Product Areas in the Medical Development Program are: 1) Equipment, 2) Pharmaceuticals/Biologics, and 3) Operational Knowledge/Concepts. The primary Program Areas of Interest are in: 1) Naval Expeditionary Health Services Support (Navy in Terrestrial, Maritime Surface, Submarine, and Aviation Operations), 2) USMC in Expeditionary Operations, and 3) Products for battlefield treatment and en route care of Combat Casualties and Combat Trauma, focusing on delivery of care within the seabase and the littoral environment.

For Product Areas 1 and 2, there are two primary acquisition strategies. The first is to test and evaluate for Naval application commercially-developed medical product or candidates in managed trials with the ultimate goal of Food and Drug Administration (FDA) approval. Partnerships with commercial developers promotes developing products of military interest for procurement by the Operating Forces. A second benefit of this strategy is that products are made available across the DoD, Federal Government, and commercial market, thus reducing overall procurement costs. During development, DoD end users are included in the process to the extent possible. The second strategy is to drive a collaborative development process with larger DoD program investments. Navy and Marine Corps needs can be met at lower service cost. This process involves developing in-house or industrial prototypes in government- managed programs to meet Naval needs while meeting regulatory requirements for production and fielding. Both tactics promote development of procurement plans that align product availability with Service integration strategies.

The Third Product Area (Knowledge/Concepts) is focused on the introduction of technologies, techniques, and procedures that enhance medical practice and standards of care for effective delivery of health care and casualty care in the Naval operating environment. These primarily require early involvement of the senior leadership of military medicine, in that the end product of the program is modification of concepts of operations, policy, and/or doctrine. These acquisitions can impact the care and performance of Sailors and Marines. Medical Development Program examples include Navy Crew Endurance Handbook and associated implementation tools.

#### E. Performance Metrics

Successful completion of Milestones/Demonstration Events for individualized project/product roadmap, on time and on budget. Ensuring dependencies across multiple efforts are maintained on schedule are primary metrics.

PE 0604771N: Medical Development

Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy

Appropriation/Budget Activity R-1 Program Element (Number/Name) Project (Number/Name)

1319 / 5 PE 0604771N / Medical Development 0000 / UNDIST

Product Developmen	it (\$ in Mi	illions)		FY 2	2017	FY 2018		FY 2019 Base		FY 2019 OCO		FY 2019 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Malaria Vaccine	SS/CR	Sanaria Inc. : Rockville, MD	0.000	3.815	Sep 2017	0.000		0.000		-		0.000	0.000	3.815	-
Malaria Vaccine	C/FFP	Various : Not Specified	0.000	0.057	Aug 2017	0.000		0.000		-		0.000	0.000	0.057	-
Individualized Fatigue Based Scheduling	SS/FFP	Pulsar Informatics : Philadelphia, PA	0.000	0.078	Jun 2017	0.000		0.000		-		0.000	0.000	0.078	-
Human Factors Individualized Fatigue Based Scheduling	Allot	Naval Submarine Medical Research Laboratory : Groton, CT	0.000	0.315	Nov 2016	0.000		0.000		-		0.000	0.000	0.315	-
Fatigue Based Scheduling	WR	Naval Post Graduate School : Monterey, CA	0.000	0.205	Dec 2016	0.000		0.000		-		0.000	0.000	0.205	-
Support of Naval Expeditionary Health Service Support (NEHSS) Modernization	Various	Various : Not Specified	0.000	0.060	Jan 2017	0.000		0.000		-		0.000	0.000	0.060	-
Future capabilities products & technologies: Management of Moderate to Severe Hemorrhage	Various	Various : Not Specified	0.000	0.358	Feb 2017	0.000		0.000		-		0.000	0.000	0.358	-
Marine Corps Systems Command Medical Products and Equipment	Various	Various : Not Specified	0.000	0.112	Jun 2017	0.000		0.000		-		0.000	0.000	0.112	-
Phage Therapy	Allot	Naval Medical Research Center : Silver Spring, MD	0.000	0.630	Jun 2017	0.000		0.000		-		0.000	0.000	0.630	-
Mitigation of Adverse Physiological Episodes	Allot	Naval Medical Research Unit : Dayton, OH	0.000	0.578	Sep 2017	0.000		0.000		-		0.000	0.000	0.578	-
		Subtotal	0.000	6.208		0.000		0.000		-		0.000	0.000	6.208	N/A

PE 0604771N: Medical Development

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy											Date: February 2018			
Appropriation/Budget Activity 1319 / 5		R-1 Program Element (Number/Name) Project (N PE 0604771N / Medical Development 0000 / UN						umber/Name) DIST						
Prior Years FY 2017				018	FY 2 Ba		FY 2		FY 2019 Total	Cost To	Total Cost	Target Value of Contract		
Project Cost Totals	0.000	6.208	0.000		0.000		-		0.000	0.000	6.208	N/A		

## Remarks

The FY2017 funding that is reflected in 0000 is erroneous due to a database error and should be reflected in project 0933.

PE 0604771N: Medical Development

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PE 0604771N: *Medical Development* Navy

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Exhibit R-4A, RDT&E Schedule Details: PB 2019 Navy	Date: February 2018		
11	,	, ,	umber/Name)
1319 / 5	PE 0604771N I Medical Development	0000 <i>I UNI</i>	DIST

# Schedule Details

	St	art	E	nd
Events by Sub Project	Quarter	Year	Quarter	Year
Proj 0000				
Preventive Medicine: Malaria Vaccine (Partner Leveraged): System Development	1	2017	4	2019
Preventive Medicine: Malaria Vaccine (Partner Leveraged): Validation of Manufacturing Scale Up	3	2017	4	2019
Patient Movement/Casualty Management: Novel Phage Therapeutics: System Development	3	2017	1	2019

Exhibit R-2A, RDT&E Project Ju	stification	PB 2019 N	lavy							Date: Febr	ruary 2018	
Appropriation/Budget Activity 1319 / 5					<b>R-1 Progra</b> PE 060477		•	•	Project (N 0933 / Med		ne) Equipment	Dev
COST (\$ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
0933: Medical/Dental Equipment Dev	22.664	2.812	9.353	8.095	-	8.095	8.214	9.067	9.291	9.520	Continuing	Continuing
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-		

### Note

The FY 2017 funding that is reflected in projects 0000 and 2896 is erroneous due to a database error and should be reflected under this project.

### A. Mission Description and Budget Item Justification

The purpose of this program 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 2019	FY 2019	FY 2019
	FY 2017	FY 2018	Base	oco	Total
Title: Medical/Dental Equipment Development	2.812	9.353	8.095	0.000	8.095
Articles:	-	_	-	-	-
FY 2018 Plans:					
-Continue system development and validation of manufacturing support for military relevant Malaria vaccine regimen production scale up.					
-Continue validation of Individual Fatigue-Based Scheduling and Countermeasure System that predicts,					
prevents, detects, and mitigates periods of high risk associated with fatigue. Individualized performance risk will be predicted and prevented by providing individual fatigue optimized schedules and mitigation strategies.					
-Continue fatigue mitigation and validation of scheduling tools to include validation of an alternative					
watchstanding schedule on Naval Surface Combatants.					
-Continue development of transitioned future capability products and technologies. Complete transition of					
technologies for management of moderate to severe hemorrhage.					
-Complete Naval Expeditionary Health Service Support: Effects of High Deck Accelerations on Surgical Tasks at					
Sea - Phase III Study.					
-Continue joint development projects with MARCORSYSCOM acquisition for medical products and equipment.					
-Continue to support phage therapy to combat antibiotic resistant bacterial infections.					
-Continue support for mitigating adverse physiological episodes to enhance safety and warfighter readiness in					
tactical aircraft.					

PE 0604771N: Medical Development

NCLASSIFIED					
			Date: Febr	uary 2018	
					Dev
in Each)	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total
ure and Fatigue Mitigation. y focus includes: 1) Enhancing Enhancing medical logistics					
asure System that predicts, dation of an alternative medical products and equipment. nfections. safety and warfighter readiness in Making under Stress. sure and Fatigue Mitigation. nary focus includes: 1) Enhancing Enhancing medical logistics					
he availability of prior year					
	R-1 Program Element (Number	R-1 Program Element (Number/Name) PE 0604771N / Medical Development  Ein Each)  Richard Stress.  In Each Stress S	R-1 Program Element (Number/Name) PE 0604771N / Medical Development  FY 2017  FY 2018  Rin Each)  Raking under Stress.  Ire and Fatigue Mitigation. If y focus includes: 1) Enhancing Enhancing medical logistics Interpretation of an alternative  Interpretation of an alternative	R-1 Program Element (Number/Name) PE 0604771N / Medical Development  FY 2017  Rin Each)  RY 2017  FY 2018  FY 2019  Base  FY 2019  Base  FY 2019  Base  FY 2019  Base  FY 2019  FY 2018  FY 2019  Base  FY 2019  Base	R-1 Program Element (Number/Name) PE 0604771N / Medical Development    In Each   Project (Number/Name)   0933 / Medical/Dental Equipment   093

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

N/A

Navy

PE 0604771N: Medical Development

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**Accomplishments/Planned Programs Subtotals** 

2.812

9.353

8.095

0.000

8.095

Exhibit R-2A, RDT&E Project Justification: PB 2019 Navy		Date: February 2018
Appropriation/Budget Activity 1319 / 5	R-1 Program Element (Number/Name) PE 0604771N / Medical Development	Project (Number/Name) 0933 / Medical/Dental Equipment Dev
131373	r L 000411 IN 1 Wedical Development	0933 i Medical/Delital Equipillelit Dev

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

#### Remarks

### D. Acquisition Strategy

The acquisition strategy for product lines and products in the Medical Development Program is designed and implemented consistent with the purpose of the particular product and with the nature and size of the investment. The Medical Development Program has a Memorandum of Agreement 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 products involves direct partnership with the acquisition and procurement professionals at Marine Corps Systems Command.

The major Product Areas in the Medical Development Program are: 1) Equipment, 2) Pharmaceuticals/Biologics, and 3) Operational Knowledge/Concepts. The primary Program Areas of Interest are in: 1) Naval Expeditionary Health Services Support (Navy in Terrestrial, Maritime Surface, Submarine, and Aviation Operations), 2) USMC in Expeditionary Operations, and 3) Products for battlefield treatment and en route care of Combat Casualties and Combat Trauma, focusing on delivery of care within the seabase and the littoral environment.

For Product Areas 1 and 2, there are two primary acquisition strategies. The first is to test and evaluate for Naval application commercially-developed medical product or candidates in managed trials with the ultimate goal of Food and Drug Administration (FDA) approval. Partnerships with commercial developers promotes developing products of military interest for procurement by the Operating Forces. A second benefit of this strategy is that products are made available across the DoD, Federal Government, and commercial market, thus reducing overall procurement costs. During development, DoD end users are included in the process to the extent possible. The second strategy is to drive a collaborative development process with larger DoD program investments. Navy and Marine Corps needs can be met at lower service cost. This process involves developing in-house or industrial prototypes in government-managed programs to meet Naval needs while meeting regulatory requirements for production and fielding. Both tactics promote development of procurement plans that align product availability with Service integration strategies.

The Third Product Area (Knowledge/Concepts) is focused on the introduction of technologies, techniques, and procedures that enhance medical practice and standards of care for effective delivery of health care and casualty care in the Naval operating environment. These primarily require early involvement of the senior leadership of military medicine, in that the end product of the program is modification of concepts of operations, policy, and/or doctrine. These acquisitions can impact the care and performance of Sailors and Marines. Medical Development Program examples include Navy Crew Endurance Handbook and associated implementation tools.

#### E. Performance Metrics

Successful completion of Milestones/Demonstration Events for individualized project/product roadmap, on time and on budget. Ensuring dependencies across multiple efforts are maintained on schedule are primary metrics.

PE 0604771N: Medical Development

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy

Appropriation/Budget Activity R-1 Program Element (Number/Name) Project (Number/Name)

1319 / 5 PE 0604771N / Medical Development 0933 / Medical/Dental Equipment Dev

Product Developmer	nt (\$ in Mi	illions)		FY 2	2017	FY 2	2018		2019 ise		2019 CO	FY 2019 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To	Total Cost	Target Value o Contrac
Malaria Vaccine	SS/CR	Sanaria, Inc. : Rockville, MD	5.984	1.100	Jan 2018	0.000		0.000		-		0.000	0.000	7.084	Continui
Malaria Vaccine	C/FFP	Various : Not Specified	0.105	0.028	Dec 2017	0.000		0.000		-		0.000	0.000	0.133	Continuir
Individualized Fatigue Based Scheduling	SS/FP	Pulsar Informatics : Philadelphia, PA	5.810	0.030	Jun 2017	0.550	Mar 2018	0.000		-		0.000	0.000	6.390	-
Human Factors Individualized Fatigue Based Scheduling	Allot	Naval Submarine Medical Research Laboratory : Groton, CT	1.541	0.100	Nov 2016	0.425	Jan 2018	0.430	Dec 2018	-		0.430	Continuing	Continuing	Continuir
Fatigue Based Scheduling	WR	Naval Post Graduate School : Monterey, CA	1.149	0.175	Dec 2016	0.390	Dec 2017	0.000		-		0.000	0.000	1.714	-
Support of Naval Expeditionary Health Service Support (NEHSS) Modernization	Various	Various : Not Specified	0.955	0.053	Jan 2017	0.000		0.000		-		0.000	0.000	1.008	Continuir
Future capabilities products & technologies: Management of Moderate to Severe Hemorrhage	Various	Various : Not Specified	0.490	0.169	Feb 2017	0.000		0.000		-		0.000	0.000	0.659	Continuir
Marine Corps Systems Command Medical Products and Equipment	Various	Various : Not Specified	0.274	0.100	Jun 2017	0.750	May 2018	0.800	Mar 2019	-		0.800	Continuing	Continuing	Continuir
Phage Therapy	Allot	Naval Med Rsrch. Cntr./Walter Reed Inst. of Rsrch. : Silver Spring, MD	0.000	0.532	Jun 2017	0.346	Dec 2017	0.000		-		0.000	0.000	0.878	Continuin
Mitigation of Adverse Physiological Episodes in Tactical Aircraft	Allot	Various : Not Specified	0.000	0.272	Sep 2017	0.995	Dec 2017	0.000		-		0.000	0.000	1.267	Continuin
Enhanced Decision Makiing Under Stress	Allot	Naval Health Research Center : San Diego, CA	0.000	0.000		0.397	Dec 2017	0.000		-		0.000	0.000	0.397	-

PE 0604771N: *Medical Development* Navy

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy

Appropriation/Budget Activity
1319 / 5

R-1 Program Element (Number/Name)
PE 0604771N / Medical Development

Date: February 2018

Project (Number/Name)
0933 / Medical/Dental Equipment Dev

Product Developmen	t (\$ in Mi	illions)		FY 2	2017	FY 2	2018	FY 2 Ba	2019 ise	FY 2	2019 CO	FY 2019 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Crew Endurance and Fatigue Mitigation	WR	Naval Post Graduate Schoo : Monterey, CA	0.000	0.000		0.750	Jan 2018	0.750	Dec 2018	-		0.750	Continuing	Continuing	Continuing
Innovative Medical Technologies and Logistics	Various	Various : Not Specified	0.000	0.000		2.899	May 2018	4.275	May 2019	-		4.275	Continuing	Continuing	Continuing
Medical Product Development	Various	Various : Not Specified	5.586	0.000	Aug 2017	0.977	Aug 2018	0.966	Aug 2019	-		0.966	Continuing	Continuing	Continuing
		Subtotal	21.894	2.559		8.479		7.221		-		7.221	Continuing	Continuing	N/A

Management Service	s (\$ in M	illions)		FY 2	2017	FY 2	2018	FY 2 Ba	2019 ise	FY 2		FY 2019 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Program Support	Various	Various : Not Specified	0.770	0.253	Aug 2017	0.874	Aug 2018	0.874	Aug 2019	-		0.874	Continuing	Continuing	Continuing
		Subtotal	0.770	0.253		0.874		0.874		-		0.874	Continuing	Continuing	N/A

	Prior Years	FY 2	017	FY 2	018	FY 2 Ba	FY 201		Cost To	Total Cost	Target Value of Contract
Project Cost Totals	22.664	2.812		9.353		8.095	-	8.095	Continuing	Continuing	N/A

#### Remarks

The FY 2019 funding request was reduced by -\$0.105 million to account for the availability of prior year execution balances.

PE 0604771N: *Medical Development* Navy

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Project (Number/Name)   Project (Number/Name)   Oss 31 Medical/Dental Equipment D   Oss 31 Medical/D	xhibit R-4, RDT&E Schedule Prof	file:	-B 2	019 Nav	'y			-					-						1						ry 20	18
Preventive Medicine: Malaria Vaccine (Partner Leveraged)    10   20   30   40   40   40   40   40   40   4																		)								ent E
Preventive Medicine: Malaria Vaccine (Partner Leveraged)  System Development  Validation of Manufacturing Scale Up  Patient Movement/Casualty Management: Novel Phage Therapeutics  System Development  Validation of Manufacturing Scale Up  Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation  Logistics  Evaluate Medical Logistics Technology	Proj 0933				<u> </u>																					
Patient Movement/Casualty Management: Novel Phage Therapeutics  System Development  Validation of Manufacturing Scale Up  Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation  Evaluate Medical Logistics Technology		1Q	2Q					2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Patient Movement/Casualty Management: Novel Phage Therapeutics  System Development  Validation of Manufacturing Scale Up  Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation  Logistics  Evaluate Medical Logistics Technology		_	ı					Scale	e Up	,														 		
Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation Logistics  Evaluate Medical Logistics Technology	Management: Novel Phage																									
Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation Logistics  Evaluate Medical Logistics Technology				sy	stem Dev	/elopr	ment																			İ
Technologies/Enhanced Medical Logistics: Next Generation Logistics  Evaluate Medical Logistics Technology						cturir	ng Scale																			
	Technologies/Enhanced Medical Logistics: Next Generation																									
2019PB - 0604771N - 0933		İ	İ		İİ	İ						Evalu	ate l	Medi	ical L	ogis	tics <sup>-</sup>	rechi	nolog	у .						İ
2019PB - 0604771N - 0933																										
	2019PB - 0604771N - 0933																									

PE 0604771N: *Medical Development* Navy

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Exhibit R-4A, RDT&E Schedule Details: PB 2019 Navy		Date: February 2018
	R-1 Program Element (Number/Name)	Project (Number/Name)
1319 / 5	PE 0604771N I Medical Development	0933 I Medical/Dental Equipment Dev

# Schedule Details

	St	art	E	nd
Events by Sub Project	Quarter	Year	Quarter	Year
Proj 0933				
Preventive Medicine: Malaria Vaccine (Partner Leveraged): System Development	1	2017	4	2019
Preventive Medicine: Malaria Vaccine (Partner Leveraged): Validation of Manufacturing Scale Up	3	2017	4	2019
Patient Movement/Casualty Management: Novel Phage Therapeutics: System Development	3	2017	1	2019
Patient Movement/Casualty Management: Novel Phage Therapeutics: Validation of Manufacturing Scale Up	1	2018	1	2019
Innovative Medical Technologies/Enhanced Medical Logistics: Next Generation Logistics: Evaluate Medical Logistics Technology	3	2018	4	2023

Exhibit R-2A, RDT&E Project Ju	stification:	PB 2019 N	lavy					Date: February 2018				
Appropriation/Budget Activity 1319 / 5					<b>R-1 Progra</b> PE 060477		•	(Number/Name) ilitary Dental Research				
COST (\$ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost
2896: Military Dental Research	0.000	0.015	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	0.015
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-		

#### Note

The FY 17 funding reflected in this project is erroneous due to a database error. This funding should be reflected in Project 0933.

### A. Mission Description and Budget Item Justification

The purpose of this program 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 firm/industry participation in the projects.

B. Accomplishments/Planned Programs (\$ in Millions, Article Quantities in Each)			FY 2019	FY 2019	FY 2019
	FY 2017	FY 2018	Base	oco	Total
Title: Medical/Dental Equipment Development	0.015	0.000	0.000	0.000	0.000
Articles:	-	-	_	-	-
<b>FY 2018 Plans:</b> N/A					
FY 2019 Base Plans: N/A					
FY 2019 OCO Plans: N/A					
FY 2018 to FY 2019 Increase/Decrease Statement: N/A					
Accomplishments/Planned Programs Subtotals	0.015	0.000	0.000	0.000	0.000

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

N/A

Navy

Remarks

PE 0604771N: Medical Development

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Exhibit R-2A, RDT&E Project Justification: PB 2019 Navy			Date: February 2018
11	, ,	, ,	umber/Name)
1319 / 5	PE 0604771N I Medical Development	2896 / Milit	tary Dental Research

### D. Acquisition Strategy

The major Product Areas in the Medical Development Program are: 1) Equipment, 2) Pharmaceuticals/Biologics, and 3) Operational Knowledge/Concepts. The primary Program Areas of Interest are in: 1) Naval Expeditionary Health Services Support (Navy in Terrestrial, Maritime Surface, Submarine, and Aviation Operations), 2) USMC in Expeditionary Operations, and 3) Products for battlefield treatment and en route care of Combat Casualties and Combat Trauma, focusing on delivery of care within the seabase and the littoral environment.

For Product Areas 1 and 2, there are two primary acquisition strategies. The first is to test and evaluate for Naval application commercially-developed medical product or candidates in managed trials with the ultimate goal of Food and Drug Administration (FDA) approval. Partnerships with commercial developers promotes developing products of military interest for procurement by the Operating Forces. A second benefit of this strategy is that products are made available across the DoD, Federal Government, and commercial market, thus reducing overall procurement costs. During development, DoD end users are included in the process to the extent possible. The second strategy is to drive a collaborative development process with larger DoD program investments. Navy and Marine Corps needs can be met at lower service cost. This process involves developing in-house or industrial prototypes in government- managed programs to meet Naval needs while meeting regulatory requirements for production and fielding. Both tactics promote development of procurement plans that align product availability with Service integration strategies.

The Third Product Area (Knowledge/Concepts) is focused on the introduction of technologies, techniques, and procedures that enhance medical practice and standards of care for effective delivery of health care and casualty care in the Naval operating environment. These primarily require early involvement of the senior leadership of military medicine, in that the end product of the program is modification of concepts of operations, policy, and/or doctrine. These acquisitions can impact the care and performance of Sailors and Marines. Medical Development Program examples include Navy Crew Endurance Handbook and associated implementation tools.

#### E. Performance Metrics

Successful completion of Milestones/Demonstration Events for individualized project/product roadmap, on time and on budget. Ensuring dependencies across multiple efforts are maintained on schedule are primary metrics.

PE 0604771N: Medical Development

Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy			Date: February 2018
Appropriation/Budget Activity	R-1 Program Element (Number/Name)	Project (N	umber/Name)
1319 / 5	PE 0604771N I Medical Development	2896 / Milit	tary Dental Research

Management Services (\$ in Millions)				FY 2	2017	FY 2018		FY 2019 Base		FY 2019 OCO					
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Program Support	Various	Various : Not Specified	0.000	0.015	Aug 2017	0.000		0.000		-		0.000	0.000	0.015	-
		Subtotal	0.000	0.015		0.000		0.000		-		0.000	0.000	0.015	N/A

	Prior Years	FY 2	2017 FY	2018	FY 2019 Base	FY 201 OCO		Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals	0.000	0.015	0.00	) (	0.000	-	0.000	0.000	0.015	N/A

### Remarks

The FY2017 funding that is reflected in 2896 is erroneous and should be reflected in project 0933.

Exhibit R-4, RDT&E Schedule Pro	ofile:	PB 2	2019	) Navy																			D	ate:	Feb	ruar	y 20	18	
Appropriation/Budget Activity 1319 / 5																( <b>Nun</b> Dev					<b>Proj</b> 2896	ect	(Nur Iilitar	nbei y De	r/ <b>Na</b> ı ental	me) Res	earc	h	
Proj 2896		FY 2017 FY 2018					FY	2019	•		FY 2	2020			FY 2021			FY 2022			FY 2023								
	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	
Program Support 2896				Program Support																									

2019PB - 0604771N - 2896

Exhibit R-4A, RDT&E Schedule Details: PB 2019 Navy			Date: February 2018
	, ,	, ,	umber/Name)
1319 / 5	PE 0604771N I Medical Development	2896 / Milit	tary Dental Research

# Schedule Details

	St	art	End				
Events by Sub Project	Quarter	Year	Quarter	Year			
Proj 2896							
Program Support 0933:	4	2017	4	2017			

Exhibit R-2A, RDT&E Project Ju	stification:	PB 2019 N	lavy					,	Date: February 2018				
Appropriation/Budget Activity 1319 / 5					_	<b>am Elemen</b> 71N <i>I Medic</i>	•	(Number/Name) ongressional Adds					
COST (\$ in Millions)	Prior Years	FY 2017	FY 2018	FY 2019 Base	FY 2019 OCO	FY 2019 Total	FY 2020	FY 2021	FY 2022	FY 2023	Cost To Complete	Total Cost	
9999: Congressional Adds	116.826	15.475	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	132.301	
Quantity of RDT&E Articles		-	-	-	-	-	-	-	-	-			

### Note

None

## A. Mission Description and Budget Item Justification

Congressional Adds: Military Dental Research

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2017	FY 2018
Congressional Add: Military Dental Research	5.803	0.000
<b>FY 2017 Accomplishments:</b> -Continued efforts in cranio-facial injury surveillance; combat dentistry; treatment of maxillofacial injury; dental disease non-battle injuries; oral/facial disease and infection in military personnel.		
FY 2018 Plans: N/A		
Congressional Add: Wound Care Research (transferred from Defense Health Program)	9.672	0.000
<b>FY 2017 Accomplishments:</b> -Continued to develop novel diagnostics and treatments to enhance the care of the wounded warfighter.		
FY 2018 Plans: N/A		
Congressional Adds Subtotals	15.475	0.000

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

N/A

Remarks

# D. Acquisition Strategy

None

## **E. Performance Metrics**

Not required for Congressional adds.

PE 0604771N: Medical Development Navy

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Navy

Appropriation/Budget Activity

1319 / 5

R-1 Program Element (Number/Name)
PE 0604771N / Medical Development

9999 / Congressional Adds

Product Developme	nt (\$ in M	illions)		FY 2017		FY 2	018	FY 2 Ba			2019 CO	FY 2019 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	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 - Wound Care Research	C/FFP	Noveome Biotherapeutics Inc. : Pittsburg, PA	22.260	9.672	Apr 2018	0.000		0.000		-		0.000	0.000	31.932	-
Congressional Add - Military Dental Research	Allot	Naval Medical Research Unit - San Antonio : San Antonio, TX	5.969	2.952	Aug 2017	0.000		0.000		-		0.000	0.000	8.921	-
Congressional Add - Military Dental Research	MIPR	USAISR Dental and Trauma Research Detachment : San Antonio, TX	5.821	2.851	Aug 2017	0.000		0.000		-		0.000	0.000	8.672	-
Congressional Adds	Various	Various : Not Specified	82.776	0.000		0.000		0.000		-		0.000	0.000	82.776	-
		Subtotal	116.826	15.475		0.000		0.000		-		0.000	0.000	132.301	N/A
			Prior					FY 2	2019	FY 2	2019	FY 2019	Cost To	Total	Target Value of

									Target
	Prior			FY 2019	FY 2019	FY 2019	Cost To	Total	Value of
	Years	FY 2017	FY 2018	Base	oco	Total	Complete	Cost	Contract
Project Cost Totals	116.826	15.475	0.000	0.000	-	0.000	0.000	132.301	N/A

Remarks

PE 0604771N: *Medical Development* Navy

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Exhibit R-4, RDT&E Schedule Prof	ile: l	PB 2	2019	Nav	y																		[	Date	: Fel	oruar	y 20	18	
Appropriation/Budget Activity 1319 / 5															emer Medic					)	<b>Pro</b> 999	<b>oject</b> 99 / (	(Nu Cong	mbe ress	r/Na iona	me) I Add	ds		
Proj 9999	FY 2017 FY 2018 FY 2		2019	19 FY 2020 FY 2021						FY 2022 FY 202				2023	:3														
	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	40	
Military Dental Research																													
Wound Care Research																													
2019PB - 0604771N - 9999	I	1	I	I	I						l	l	I	I	I		l												

PE 0604771N: *Medical Development* Navy

**UNCLASSIFIED** 

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Exhibit R-4A, RDT&E Schedule Details: PB 2019 Navy			Date: February 2018		
	, , , , , , , , , , , , , , , , , , , ,	- , (	lumber/Name)		
1319 / 5	PE 0604771N I Medical Development	9999 / Con	ngressional Adds		

# Schedule Details

	St	art	End			
Events by Sub Project	Quarter	Year	Quarter	Year		
Proj 9999						
Military Dental Research: Schedule Detail	4	2017	4	2018		
Wound Care Research: Schedule Detail	3	2018	4	2018		