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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2024 Defense Health Agency **Date:** March 2023

<b>Appropriation/Budget Activity</b> 0130: <i>Defense Health Program I BA 2: RDT&amp;E</i>	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA I <i>Medical Products and Support Systems Development</i>
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
Total Program Element	65.786	20.775	64.030	58.712	0.000	58.712	58.102	62.395	63.256	64.523	Continuing	Continuing
500A: <i>CSI - Congressional Special Interests</i>	5.351	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
375: <i>GDF - Medical Products and Support System Development</i>	60.435	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
375A: <i>GDF - Medical Simulation and Training</i>	0.000	2.000	2.000	2.000	0.000	2.000	2.000	2.000	2.040	2.081	Continuing	Continuing
375B: <i>GDF - Medical Readiness</i>	0.000	10.000	5.125	5.674	0.000	5.674	5.967	7.490	7.641	7.794	Continuing	Continuing
375C: <i>GDF - Medical Combat Support</i>	0.000	8.775	13.871	14.683	0.000	14.683	14.838	13.770	14.045	14.326	Continuing	Continuing
375D: <i>GDF - Medical Products and Support System Development</i>	0.000	0.000	43.034	36.355	0.000	36.355	35.297	39.135	39.530	40.322	Continuing	Continuing

**A. Mission Description and Budget Item Justification**

Guidance for Development of the Force – Medical Products and Support Systems Development: This program element (PE) provides funding for system development and demonstration of medical commodities delivered from the various medical advanced development and prototyping Department of Defense (DoD) Components that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials for products that require US Food and Drug Administration approval.

Development, test, and evaluation in this PE is designed to address requirements identified through the Joint Capabilities Integration and Development System and other Department of Defense operational needs. Medical development, test, and evaluation priorities for the Defense Health Program (DHP) are guided by, and will support, the National Defense Strategy, the Joint Staff Surgeon’s Joint Concept for Health Services, and other overarching DoD strategic framework documents.

Coordination occurs through the planning and execution activities of the Defense Health Agency Component Acquisition Executive (DHA CAE) as the Milestone Decision Authority for medical materiel development efforts. As technologies mature, the most promising efforts will transition to production and deployment.

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<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
Previous President's Budget	21.489	64.030	58.712	-	58.712
Current President's Budget	20.775	64.030	58.712	-	58.712
Total Adjustments	-0.714	0.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-0.714	-			

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

**Project:** 375D: *GDF - Medical Products and Support System Development*  
 Congressional Add: *GDF - Medical Products and Support System Development*

	<b>FY 2022</b>	<b>FY 2023</b>
Congressional Add Subtotals for Project: 375D	0.000	-
Congressional Add Totals for all Projects	0.000	-

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**Exhibit R-2A, RDT&E Project Justification:** PB 2024 Defense Health Agency **Date:** March 2023

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / <i>Medical Products and Support Systems Development</i>	<b>Project (Number/Name)</b> 500A / <i>CSI - Congressional Special Interests</i>
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
500A: <i>CSI - Congressional Special Interests</i>	5.351	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

**A. Mission Description and Budget Item Justification**

In FY 2019, the Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2018 Congressionally-directed research program is to stimulate innovative research through a competitive, focused, peer-reviewed medical research at intramural and extramural research sites. Because of the CSI annual structure, out-year funding is not programmed.

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

N/A

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2024 Defense Health Agency										<b>Date:</b> March 2023		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / Medical Products and Support Systems Development				<b>Project (Number/Name)</b> 375 / GDF - Medical Products and Support System Development			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>FY 2028</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
375: GDF - Medical Products and Support System Development	60.435	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

**Note**

Starting in FY2022, Project 375 was realigned into Projects 375A, 375B, and 375C.

**A. Mission Description and Budget Item Justification**

Guidance for Development of the Force-Medical Products and Support Systems Development: This funding supports materiel development activities that further system development and demonstration prior to initial full rate production and fielding of commodities.

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

	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
<b>Title:</b> GDF - Medical Products and Support Systems Development (GDF-MPSSD)	0.000	0.000	0.000	0.000	0.000
<b>Description:</b> GDF-Medical Products and Support Systems Development: This funding supports activities to support system development and demonstration prior to initial full rate production and fielding of medical commodities delivered from 0604110HP (Medical Products Support and Advanced Concept Development). Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.					
<b>FY 2023 Plans:</b> N/A					
<b>FY 2024 Base Plans:</b> N/A					
<b>FY 2024 OCO Plans:</b> N/A					
<b>FY 2023 to FY 2024 Increase/Decrease Statement:</b> N/A					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	0.000	0.000	0.000	0.000

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2024 Defense Health Agency		<b>Date:</b> March 2023
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / <i>Medical Products and Support Systems Development</i>	<b>Project (Number/Name)</b> 375 / <i>GDF - Medical Products and Support System Development</i>

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

N/A

**Remarks**

N/A

**D. Acquisition Strategy**

N/A

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**Exhibit R-2A, RDT&E Project Justification:** PB 2024 Defense Health Agency **Date:** March 2023

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / Medical Products and Support Systems Development	<b>Project (Number/Name)</b> 375A / GDF - Medical Simulation and Training
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
375A: GDF - Medical Simulation and Training	0.000	2.000	2.000	2.000	0.000	2.000	2.000	2.000	2.040	2.081	Continuing	Continuing

**Note**  
Starting in FY 2022, Project 375A was realigned from Project 375. This Project is not a new start.

**A. Mission Description and Budget Item Justification**

Guidance for Development of the Force-Medical Simulation and Training: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<b>Title:</b> GDF - Medical Simulation and Training	2.000	2.000	2.000	0.000	2.000
<b>Description:</b> GDF-Medical Products and Support Systems Development: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical simulation delivered from 0604110HP (Medical Simulation and Training, Advanced Concept Development). Materiel development may include accelerated transition of Medical Simulation products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical training systems technologies.					
<b>FY 2023 Plans:</b> Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. Medical Simulation Training Systems will begin to develop standardized training capabilities for point of injury, trauma simulation, hospital training, along with a common platform architecture that improves medical care across the DoD.					
<b>FY 2024 Base Plans:</b> FY2024 plans continue efforts as outlined in FY 2023 and support the development and demonstration of medical simulation capabilities.					
<b>FY 2024 OCO Plans:</b> N/A					
<b>FY 2023 to FY 2024 Increase/Decrease Statement:</b>					

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2024 Defense Health Agency		<b>Date:</b> March 2023
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / <i>Medical Products and Support Systems Development</i>	<b>Project (Number/Name)</b> 375A / <i>GDF - Medical Simulation and Training</i>

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
No increase from FY23 to FY24.					
<b>Accomplishments/Planned Programs Subtotals</b>	2.000	2.000	2.000	0.000	2.000

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

N/A

**Remarks**

N/A

**D. Acquisition Strategy**

This program will test and evaluate medical simulation products and platforms developed in order to review data for operational and clinical use prior to production and fielding.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2024 Defense Health Agency **Date:** March 2023

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / Medical Products and Support Systems Development	<b>Project (Number/Name)</b> 375B / GDF - Medical Readiness
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
375B: GDF - Medical Readiness	0.000	10.000	5.125	5.674	0.000	5.674	5.967	7.490	7.641	7.794	Continuing	Continuing

**Note**  
Starting in FY 2022, Project 375B was realigned from Project 375. This Project is not a new start.

**A. Mission Description and Budget Item Justification**

Guidance for Development of the Force-Medical Readiness: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

**Title:** GDF - Medical Readiness

**Description:** GDF-Medical Readiness: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical readiness capability delivered from 0604110HP (Medical Readiness, Advanced Concept Development). Materiel development may include accelerated transition of Medical Readiness products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical readiness systems technologies.

**FY 2023 Plans:**

Programs will focus on prevention of illness and injury along with optimization of human performance. The Health Readiness and Performance System will continue to refine technologies including wearable sensors to monitor non-diagnostic physiologic data in real-time to improve Warfighter health, readiness and performance, reduce casualties, and increase situational awareness. The program will transition wearable system programs under its integrated system; COVID-19 pilot study using algorithms developed to provide early warning of COVID-19 infection. The Enterotoxigenic E. Coli Vaccine program plans to continue development on the only FDA-approved preventative vaccine providing protection from 90% of ETEC strains. In FY23, the program will hold an End of Phase 2 meeting with the FDA, award an EMD phase contract, initiate Phase 3 clinical study, and continue planning for a Controlled Human Infection Model. The Breath Test for Pulmonary Oxygen Toxicity program seeks to test for pulmonary oxygen toxicity in order to enhance oxygen supplementation, which is used

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
	10.000	5.125	5.674	0.000	5.674

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<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / <i>Medical Products and Support Systems Development</i>	<b>Project (Number/Name)</b> 375B / <i>GDF - Medical Readiness</i>

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
widely to support clinical and operational efforts within the DOD. In FY23, the program will continue integration and development testing and plans to increase its TRL level.  <b>FY 2024 Base Plans:</b> FY2024 plans continue efforts as outlined in FY 2023 and support the development and demonstration of medical readiness capabilities.  <b>FY 2024 OCO Plans:</b> N/A  <b>FY 2023 to FY 2024 Increase/Decrease Statement:</b> No increase from FY23 to FY24.					
<b>Accomplishments/Planned Programs Subtotals</b>	10.000	5.125	5.674	0.000	5.674

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

N/A

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2024 Defense Health Agency **Date:** March 2023

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / Medical Products and Support Systems Development	<b>Project (Number/Name)</b> 375C / GDF - Medical Combat Support
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COST (\$ in Millions)	Prior Years	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total	FY 2025	FY 2026	FY 2027	FY 2028	Cost To Complete	Total Cost
375C: GDF - Medical Combat Support	0.000	8.775	13.871	14.683	0.000	14.683	14.838	13.770	14.045	14.326	Continuing	Continuing

**Note**  
Starting in FY 2022, Project 375C was realigned from Project 375. This Project is not a new start.

**A. Mission Description and Budget Item Justification**

Guidance for Development of the Force-Medical Combat Support: This funding supports material development activities that enhance system development and demonstration prior to initial full rate production and fielding of capabilities.

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<b>Title:</b> GDF - Medical Combat Support	8.775	13.871	14.683	0.000	14.683
<b>Description:</b> GDF-Medical Combat Support: This funding enhances activities to support system development and demonstration prior to initial full rate production and fielding of medical readiness capability delivered from 0604110HP (Medical Combat Support, Advanced Concept Development). Materiel development may include accelerated transition of Medical Combat Support products through clinical and field validation studies, advanced prototyping, risk reduction, operational test and evaluation, manufacturing, and product transition efforts for medical information technology applications and medical combat support systems technologies.					
<b>FY 2023 Plans:</b> The Traumatic Brain Injury Assessment & Diagnosis – Mobile Applications program is being developed to offer a suite of applications on a mobile device to assess and monitor SMs after a suspected traumatic brain injury event, suspected psychological health event, and/or an event linked to cognitive impairment. In FY23, the program will continue platform development for the integration of mobile apps based on validated requirements and end user feedback. The Battlefield Pain Management – Ketamine Program seeks to continue development on a rapid-acting non-opioid treatment to combat battlefield pain during tactical field care and casualty evacuation with a superior safety profile compared to conventionally used opioid pain medications. In FY23, the program will submit its CDD into staffing, meet with the FDA for a Clinical Hold Type A meeting, and initiate non-clinical toxicology studies.					
<b>FY 2024 Base Plans:</b>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
FY2024 plans continue efforts as outlined in FY 2023 and support the development and demonstration of medical combat support capabilities.  <b>FY 2024 OCO Plans:</b> N/A  <b>FY 2023 to FY 2024 Increase/Decrease Statement:</b> Increase due to inflation program growth.					
<b>Accomplishments/Planned Programs Subtotals</b>	8.775	13.871	14.683	0.000	14.683

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

N/A

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate medical products in government-managed clinical trials in order to gather data to meet military and regulatory (e.g., FDA, Environmental Protection Agency) requirements for production and fielding.

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2024 Defense Health Agency										<b>Date:</b> March 2023		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0605145DHA / Medical Products and Support Systems Development			<b>Project (Number/Name)</b> 375D / GDF - Medical Products and Support System Development				
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>FY 2028</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
375D: GDF - Medical Products and Support System Development	0.000	0.000	43.034	36.355	0.000	36.355	35.297	39.135	39.530	40.322	Continuing	Continuing

**A. Mission Description and Budget Item Justification**

Funding and mission realignment of US Army Medical Research and Development Command transfer to the Defense Health Agency in order to meet Congressional intent as outlined in NDAA 2019 (Section 711) and NDAA 2020 (Section 737) in support of Medical Products and Support System Development.

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

	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
<b>Title:</b> GDF - Medical Products and Support System Development	0.000	43.034	36.355	0.000	36.355
<b>Description:</b> Programmatic transfer in accordance with the 711/737 US Army Medical Research and Development Command transfer to Defense Health Agency in support of Medical Products and Support System Development from Army PEs 0604807A. Funding is provided for engineering and manufacturing development of diagnostic devices, medical products for enhanced combat casualty care and follow on products, including blood products and for the development of candidate medical countermeasures for military relevant infectious diseases focusing on prevention and treatment to increase medical readiness. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of vaccines, drugs and medical devices.					
<b>FY 2023 Plans:</b> Programs will focus on System Development and Demonstration in support of Medical Products and Support Systems.					
<b>FY 2024 Base Plans:</b> Programs will focus on system development and demonstration in support of medical solutions. Significant FY24 Programs: Freeze Dried Plasma, Ultrasound Field Portable, Cryopreserved Platelets, and Malaria Treatment Drug - Intravenous Artesunate.					
<b>FY 2024 OCO Plans:</b> N/A					
<b>FY 2023 to FY 2024 Increase/Decrease Statement:</b>					

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2022</b>	<b>FY 2023</b>	<b>FY 2024 Base</b>	<b>FY 2024 OCO</b>	<b>FY 2024 Total</b>
Funding decrease for this Project was due to a realignment of the development mission.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	43.034	36.355	0.000	36.355
	<b>FY 2022</b>	<b>FY 2023</b>			
<b>Congressional Add:</b> GDF - Medical Products and Support System Development	0.000	-			
<b>FY 2022 Accomplishments:</b> N/A					
<b>Congressional Adds Subtotals</b>	0.000	-			

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

N/A

**Remarks**

N/A

**D. Acquisition Strategy**

N/A