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**Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Defense Health Agency** **Date:** May 2021

**Appropriation/Budget Activity**  
0130: *Defense Health Program I BA 2: RDT&E* **R-1 Program Element (Number/Name)**  
PE 0604110DHA I *Medical Products Support and Advanced Concept Development*

<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
Total Program Element	1,423.290	1,174.955	147.331	142.252	-	142.252	-	-	-	-	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	401.343	1,036.900	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
434A: <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>	22.617	4.000	4.080	4.162	-	4.162	-	-	-	-	Continuing	Continuing
374: <i>GDF - Medical Products Support and Advanced Concept Development</i>	999.330	124.055	128.251	0.000	-	0.000	-	-	-	-	Continuing	Continuing
374A: <i>GDF - Medical Simulation and Training</i>	-	0.000	0.000	18.490	-	18.490	-	-	-	-	Continuing	Continuing
374B: <i>GDF - Medical Readiness</i>	-	-	-	48.816	-	48.816	-	-	-	-	Continuing	Continuing
374C: <i>GDF - Medical Combat Support</i>	-	0.000	0.000	49.661	-	49.661	-	-	-	-	Continuing	Continuing
374D: <i>GDF - Restoration &amp; Healthcare Systems</i>	-	0.000	0.000	21.123	-	21.123	-	-	-	-	Continuing	Continuing
520: <i>CARES Act - H.R. 748, (P.L. 116-136)</i>	-	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
464: <i>CSI - Congressional Special Interests</i>	-	0.000	15.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing
441: <i>CSI- Joint Warfighter Medical Research</i>	-	10.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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

Guidance for Development of the Force - Medical Products Support and Advanced Concept Development: This program element (PE) provides funding to support: advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<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 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i>
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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.

Program development and execution is coordinated with all of the Military Services and Special Operations Command, appropriate Defense agencies or activities and other federal agencies, to include the Department of Veterans Affairs, the Department of Health and Human Services, and the Department of Homeland Security. 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 medical products and support systems development funding, PE 0605145.

<b>B. Program Change Summary (\$ in Millions)</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>
Previous President's Budget	138.055	132.331	142.252	-	142.252
Current President's Budget	1,174.955	147.331	142.252	-	142.252
Total Adjustments	1,036.900	15.000	0.000	-	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	1,036.900	15.000			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-	-			

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

**Project:** 400Z: *CSI - Congressional Special Interests*

Congressional Add: 441A - *Joint Warfighter Medical Research Program*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

	<b>FY 2020</b>	<b>FY 2021</b>
	1,036.900	-
	1,036.900	-
	1,036.900	-

**Change Summary Explanation**

Project 520 was created for CARE Act funding.

\$936.900M of CARE Act DHP O&M funding was reprogrammed into Project 520 for RDTE purposes.

\$35.741M of 6.3 RDTE funding was reprogrammed into Project 520 for RDTE CARE ACT purposes.

\$64.042M of 6.3 RDTE funding was reprogrammed into Project 464 for RDTE CARE ACT purposes.

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency										<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				<b>Project (Number/Name)</b> 400Z / <i>CSI - Congressional Special Interests</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years (+)</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
400Z: <i>CSI - Congressional Special Interests</i>	401.343	1,036.900	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

(+) The sum of all Prior Years is \$634.657 million less than the represented total due to several projects ending

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

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)**

	<b>FY 2020</b>	<b>FY 2021</b>
<b>Congressional Add:</b> 441A - Joint Warfighter Medical Research Program	1,036.900	-
<b>FY 2020 Accomplishments:</b> CSI Add		
<b>Congressional Adds Subtotals</b>	1,036.900	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

Prior year CSI funded research will be assessed for developmental maturity and qualification for initial or continued advanced development funding. If advanced development criteria are met, follow-on development will be solicited through a peer-reviewed process.

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency										<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				<b>Project (Number/Name)</b> 434A / <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
434A: <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>	22.617	4.000	4.080	4.162	-	4.162	-	-	-	-	Continuing	Continuing

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

This project focuses on coordinating the activities to rapidly field advanced medical capabilities to meet the needs of warfighters while bridging the gap between science and technology (S&T) and development, fielding, and sustainment. This project enables the fielding of advanced medical capabilities (Technology Readiness Level-TRL 5-7) to address the vital medical readiness needs of our Airmen. Development, modification, and modernization projects emphasize technologies supporting the Air Force (AF) Surgeon General's aerospace & operational medicine and medical readiness priorities. This project ensures viability of S&T and translational research efforts with materiel components by providing programmed funding for logical progression and transition of those activities into the product development lifecycle and into the hands of AF end-users.

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

	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<b>Title:</b> Air & Space Medical Readiness Advanced Concept Development (AF)	4.000	4.080	4.162
<b>Description:</b> This project ensures balance, rigor, and timely fielding of medical capabilities in the AF Advanced Development portfolio. This project focuses on the advancement of Engineering and Manufacturing Development (EMD) for prototypes and production representative units that address AF capability gaps in aerospace and operational medicine and medical readiness.			
<b>FY 2021 Plans:</b> Continue materiel developments of the: a) Trauma-Specific Vascular Shunt device for restoring blood flow to extremities post trauma during en route care; b) Biomeme Pathogen Surveillance System, a far-forward hand-held diagnostics and detection capability for AF relevant pathogens; c) Spinal Injury Transport – Device (SIT-D), a man-portable immobilization device for use in the en route care system; and d) the Automated Vision Tester (AVT), a state-of-the art vision tester for measurable and meaningful specs for Airman vision standards. Begin assessment and development of medical materiel efforts including, but not limited to, autonomous closed-loop control of oxygen and ventilation intervention during en route patient care and on-demand sterile water for injection and Intravenous (IV) solutions in deployed Expeditionary Medical Support System (EMEDS). Transition to the AF Warfighter the following capabilities: Flashing Indicators of Swimmer's Health (FISH) and the Patient Loading System (PLS).			
<b>FY 2022 Plans:</b> FY22 plans continue efforts as outlined in FY 2021.			
<b>FY 2021 to FY 2022 Increase/Decrease Statement:</b>			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 434A / <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Funding increase due to inflation.				
<b>Accomplishments/Planned Programs Subtotals</b>		4.000	4.080	4.162
<b>C. Other Program Funding Summary (\$ in Millions)</b>				
N/A				
<b>Remarks</b>				
Accomplishments: Made significant advancements towards the materiel development of the Patient Loading System (PLS), an en route care ramp system for on- / off-boarding with high deck aircraft. Additionally, the Field Intravenous Expeditionary System yielded two prototypes that are undergoing early operational assessments prior to entry into Phase III / EMD and Design Freeze Optimization. Lastly, the Automated Vision Tester (AVT) and the Flashing Indicator of Swimmers' Health (FISH) projects have either reached or are nearing prototype design and are set to begin EMD prior to the close of CY20.				
<b>D. Acquisition Strategy</b>				
Partnerships with Defense Health Agency/Component Acquisition Executive (DHA/CAE), the U.S. Army Medical Research & Development Command (USAMRMC), U.S. Army Medical Research Acquisition Activity (USAMRAA), Navy Medical Research Center (NMRC), Air Force Research Laboratory (AFRL), Air Force Life Cycle Management Center (AFLCMC), Department of the Interior (interagency cooperative agreements and use award of delivery orders and task assignments) and medical technology consortiums to perform engineering, manufacturing, and prototype development Indefinite Delivery, Indefinite Quality (IDIQ) vehicles to include those awarded under Small Business Innovation Research (SBIR) phase III provisions. Utilization of SBIR program direct awards for Phase III transition efforts and a Cooperative Agreement structure through foundations supporting military medical research and development programs. Will utilize industry-standard project management processes and DoD Acquisition process managed by the AFLCMC, Wright-Patterson AFB.				

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency										<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				<b>Project (Number/Name)</b> 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
374: <i>GDF - Medical Products Support and Advanced Concept Development</i>	999.330	124.055	128.251	0.000	-	0.000	-	-	-	-	Continuing	Continuing

**Note**

Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.

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

Guidance for Development of the Force-Medical Products Support and Advanced Concept Development: This funding supports materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record; and medical simulation and training system technologies.

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

	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<b>Title:</b> GDF – Medical Product Support and Advanced Concept Development	124.055	128.251	0.000
<b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications and medical training systems technologies.			
<b>FY 2021 Plans:</b>			
Medical Simulation and Training: Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. The Point-of-Injury and Trauma Simulation program will continue capability development tying together individual, collective, service and Joint training to Warfighters and Medical Professionals across the Department of Defense. The Hospital Training Simulation Systems and Evacuation and Transportation Simulation Systems programs will continue to develop, standardize and baseline the Medical Treatment Facility, Theater Hospital training (care and procedures), and en-route patient care training for interoperability. The Learning, Tactics and Technology Systems program will continue to develop the training courses, hands-on training, and exercises to develop and maintain military medical skills that enhance and maximize the training simulations, manikins and healthcare across the Department of Defense.			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i>		
<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>		<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<p>Medical Readiness: Programs will focus on prevention of illness and injury along with optimization of human performance. The Pharmaceutical Intervention for Noise-Induced Hearing Loss-Acute Exposure Treatment program will continue development of the Capability Development Document with Key Performance Parameters and continue progress with an on-going clinical trial with a promising drug treatment candidate. The Broad Spectrum Snake Bite antidote initiates clinical trials to elevate safety and effectiveness of the capability.</p> <p>Medical Combat Support: Programs will focus on operational support. The Hemorrhage Detection program will continue development of the Capability Development Document with Key Performance Parameters along with a laboratory-based technology analysis study to inform ability for the capability to be deployed to Roles 1-3. The Traumatic Brain Injury (TBI) Assessment and Diagnosis program will continue to integrate information from end user feedback, field evaluations in the deployed environment, and market research to identify a solution to aid the medical provider in the ability to triage and monitor a moderate/severe TBI. The Non-Compressible Hemorrhage Control program will continue to expand as a family of systems approach to identify potential solutions that would fulfill this gap. Efficacy of developmental items will be evaluated in clinical studies. The Joint Medical Exchange and Documentation of Information for Combat Casualty Care program will continue to conduct prototype demonstrations in operational and simulated field environments. Initiate K-9 blood product and Multi Channel Infusion Pump capability efforts.</p> <p>Restoration and Healthcare Systems: Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. The Traumatic Brain Injury-Drug Treatment program will continue to evaluate market research to identify possible TBI drug candidates that are ready for focused Phase II clinical trials and conduct clinical trial planning. The Post Traumatic Stress Disorder-Drug Treatment program will continue to explore options for simultaneous testing of multiple drugs using an innovative testing design.</p> <p><b>FY 2022 Plans:</b> Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.</p>				
<b>Accomplishments/Planned Programs Subtotals</b>		124.055	128.251	0.000
<b>C. Other Program Funding Summary (\$ in Millions)</b>				
N/A				
<b>Remarks</b>				

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i>

**D. Acquisition Strategy**

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / Medical Products Support and Advanced Concept Development	<b>Project (Number/Name)</b> 374A / GDF - Medical Simulation and Training
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
374A: GDF - Medical Simulation and Training	-	0.000	0.000	18.490	-	18.490	-	-	-	-	Continuing	Continuing

**Note**  
Starting in FY 2022, funding for Project 374A was realigned from Projects 374. 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 materiel development of products that provide solutions for the most pressing simulation and training needs of the Warfighter through advanced concept development and prototyping of medical products and medical information technology applications in direct support of MHS Beneficiaries.

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

	FY 2020	FY 2021	FY 2022
<p><b>Title:</b> GDF - Medical Simulation and Training</p> <p><b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical simulation and training needs of the warfighter. Materiel development may include accelerated transition of simulation and training capabilities along with medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications and medical training systems technologies.</p> <p><b>FY 2022 Plans:</b> Programs will focus on development and application of medical simulation and training capabilities for hospital care and operations. The Point-of-Injury and Trauma Simulation program will continue capability development tying together individual, collective, service and Joint training to Warfighters and Medical Professionals across the Department of Defense. The Hospital Training Simulation Systems and Evacuation and Transportation Simulation Systems programs will continue to develop, standardize and baseline the Medical Treatment Facility, Theater Hospital training (care and procedures), and en-route patient care training for interoperability. The Learning, Tactics and Technology Systems program will continue to develop the training courses, hands-on training, and exercises to develop and maintain military medical skills that enhance and maximize the training simulations, manikins and healthcare across the Department of Defense.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Funding for Project 374A was realigned from Projects 374</p>	-	-	18.490
<b>Accomplishments/Planned Programs Subtotals</b>	-	-	18.490

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<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374A / <i>GDF - Medical Simulation and Training</i>

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

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate medical support systems, medical information technologies, and simulation and training capabilities in operational and clinical user assessments to gather data required for military and regulatory requirements prior to production and fielding.

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency										<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / Medical Products Support and Advanced Concept Development				<b>Project (Number/Name)</b> 374B / GDF - Medical Readiness			
<b>COST (\$ in Millions)</b>	<b>Prior Years (+)</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
374B: GDF - Medical Readiness	-	-	-	48.816	-	48.816	-	-	-	-	Continuing	Continuing

(+) The sum of all Prior Years is \$0.000 million less than the represented total due to several projects ending

**Note**

Starting in FY 2022, funding for Project 374B was realigned from Projects 374. This Project is not a new start.

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

Guidance for Development of the Force-Medical Products Support and Advanced Concept Development: This funding supports materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record.

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

	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<b>Title:</b> GDF - Medical Readiness	-	-	48.816
<b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications.			
<b>FY 2022 Plans:</b> Programs will focus on prevention of illness and injury along with optimization of human performance. The Pharmaceutical Intervention for Noise-Induced Hearing Loss-Acute Exposure Treatment program will continue development of the Capability Development Document with Key Performance Parameters and continue progress with an on-going clinical trial with a promising drug treatment candidate. Continue Broad Spectrum Snake Bite antidote clinical trials to elevate safety and effectiveness of the capability.			
<b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Funding for Project 374B was realigned from Projects 374.			
<b>Accomplishments/Planned Programs Subtotals</b>			48.816

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

N/A

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374B / <i>GDF - Medical Readiness</i>

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

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency										<b>Date:</b> May 2021		
<b>Appropriation/Budget Activity</b> 0130 / 2					<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				<b>Project (Number/Name)</b> 374C / <i>GDF - Medical Combat Support</i>			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022 Base</b>	<b>FY 2022 OCO</b>	<b>FY 2022 Total</b>	<b>FY 2023</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
374C: <i>GDF - Medical Combat Support</i>	-	0.000	0.000	49.661	-	49.661	-	-	-	-	Continuing	Continuing

**Note**

Starting in FY 2022, funding for Project 374C was realigned from Projects 374. This Project is not a new start.

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

Guidance for Development of the Force-Medical Products Support and Advanced Concept Development: This funding supports materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record.

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

<b>Title:</b> GDF - Medical Combat Support	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
<b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications.	-	-	49.661
<b>FY 2022 Plans:</b> Programs will focus on operational support. The Hemorrhage Detection program will continue development of the Capability Development Document with Key Performance Parameters along with a laboratory-based technology analysis study to inform ability for the capability to be deployed to Roles 1-3. The Traumatic Brain Injury (TBI) Assessment and Diagnosis program will continue to integrate information from end user feedback, field evaluations in the deployed environment, and market research to identify a solution to aid the medical provider in the ability to triage and monitor a moderate/severe TBI. The Non-Compressible Hemorrhage Control program will continue to expand as a family of systems approach to identify potential solutions that would fulfill this gap. Efficacy of developmental items will be evaluated in clinical studies. The Joint Medical Exchange and Documentation of Information for Combat Casualty Care program will continue to conduct prototype demonstrations in operational and simulated field environments. Also, continue the K-9 blood product and Multi Channel Infusion Pump capability efforts.			
<b>FY 2021 to FY 2022 Increase/Decrease Statement:</b>			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374C / <i>GDF - Medical Combat Support</i>

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2022</b>
Funding for Project 374C was realigned from Projects 374.			
<b>Accomplishments/Planned Programs Subtotals</b>	-	-	49.661

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

N/A

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.

**UNCLASSIFIED**

**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / Medical Products Support and Advanced Concept Development	<b>Project (Number/Name)</b> 374D / GDF - Restoration & Healthcare Systems
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
374D: GDF - Restoration & Healthcare Systems	-	0.000	0.000	21.123	-	21.123	-	-	-	-	Continuing	Continuing

**Note**

Starting in FY 2022, funding for Project 374D was realigned from Projects 374. This Project is not a new start.

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

Guidance for Development of the Force-Medical Products Support and Advanced Concept Development: This funding supports materiel development of products that provide solutions for the most pressing medical needs of the Warfighter through advanced concept development of medical products that are regulated by the US Food and Drug Administration (FDA); clinical and field validation studies supporting the transition of FDA-licensed and unregulated products and medical practice guidelines to the military operational user; prototyping; risk reduction and product transition efforts for medical information technology applications such as coordination with the Program Execution Offices for integration of medical aspects into other acquisition Programs of Record.

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

<b>Title:</b> GDF - Restoration & Healthcare Systems	FY 2020	FY 2021	FY 2022
<p><b>Description:</b> This funding provides product support and advanced concept development of materiel products that meet the medical needs of the warfighter. Materiel development may include accelerated transition of US Food and Drug Administration (FDA)-licensed and unregulated products and medical practice guidelines to the military operational user through clinical and field validation studies, prototyping, risk reduction, and product transition efforts for medical information technology applications.</p> <p><b>FY 2022 Plans:</b> Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. The Traumatic Brain Injury-Drug Treatment program will continue to evaluate market research to identify possible TBI drug candidates that are ready for focused Phase II clinical trials and conduct clinical trial planning. The Post Traumatic Stress Disorder-Drug Treatment program will continue to explore options for simultaneous testing of multiple drugs using an innovative testing design. Continued clinical trials for effectiveness of bacteriophage treatment for bacteria infections.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Funding for Project 374D was realigned from Projects 374. This Project is not a new start.</p>	-	-	21.123
<b>Accomplishments/Planned Programs Subtotals</b>	-	-	21.123

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

N/A

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Defense Health Agency		<b>Date:</b> May 2021
<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 374D / <i>GDF - Restoration &amp; Healthcare Systems</i>

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

**Remarks**

**D. Acquisition Strategy**

This program will test and evaluate pharmaceuticals, devices, medical support systems, and medical information technologies in government-managed clinical trials and user assessments to gather data required for military and regulatory requirements prior to production and fielding, to include FDA approval, Environmental Protection Agency registration, and safe-to-fly evaluation.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 520 / <i>CARES Act - H.R. 748, (P.L. 116-136)</i>
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
520: <i>CARES Act - H.R. 748, (P.L. 116-136)</i>	-	0.000	0.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

**Note**

Congressional Add: CARES Act - H.R. 748, (P.L. 116-136)

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

CARES Act - H.R. 748, (P.L. 116-136)

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

N/A

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**UNCLASSIFIED**

**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / Medical Products Support and Advanced Concept Development	<b>Project (Number/Name)</b> 464 / CSI - Congressional Special Interests
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
464: CSI - Congressional Special Interests	-	0.000	15.000	0.000	-	0.000	-	-	-	-	Continuing	Continuing

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

CARES Act - H.R. 748, (P.L. 116-136)

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

	FY 2020	FY 2021	FY 2022
<b>Title:</b> CARES Act - H.R. 748, (P.L. 116-136)	-	15.000	-
<b>Description:</b> CARES Act - H.R. 748, (P.L. 116-136)  Reprogramming in support of COVID vaccine capabilities and wearables.			
<b>FY 2021 Plans:</b> Reprogramming in support of COVID vaccine capabilities and wearables.			
<b>FY 2021 to FY 2022 Increase/Decrease Statement:</b> Increase due to inflation.			
<b>Accomplishments/Planned Programs Subtotals</b>	-	15.000	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A

**UNCLASSIFIED**

**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Defense Health Agency **Date:** May 2021

<b>Appropriation/Budget Activity</b> 0130 / 2	<b>R-1 Program Element (Number/Name)</b> PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	<b>Project (Number/Name)</b> 441 / <i>CSI- Joint Warfighter Medical Research</i>
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COST (\$ in Millions)	Prior Years	FY 2020	FY 2021	FY 2022 Base	FY 2022 OCO	FY 2022 Total	FY 2023	FY 2024	FY 2025	FY 2026	Cost To Complete	Total Cost
441: <i>CSI- Joint Warfighter Medical Research</i>	-	10.000	0.000	0.000	-	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

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

Congressional Add In

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

	FY 2020	FY 2021	FY 2022
<b>Title:</b> CSI- Joint Warfighter Medical Research	10.000	-	-
<b>Description:</b> Congressional Add In			
<b>Accomplishments/Planned Programs Subtotals</b>	10.000	-	-

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A