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**Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Defense Health Agency** **Date:** April 2022

**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 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
Total Program Element	745.966	149.831	197.360	166.960	0.000	166.960	172.289	175.432	179.073	182.384	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	401.343	5.000	49.500	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
374: <i>GDF - Medical Products Support and Advanced Concept Development</i>	332.623	131.517	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing
374A: <i>GDF - Medical Simulation and Training</i>	0.000	0.000	18.490	18.440	0.000	18.440	17.470	16.460	17.020	17.360	Continuing	Continuing
374B: <i>GDF - Medical Readiness</i>	0.000	0.000	48.816	69.157	0.000	69.157	83.101	74.568	77.893	79.452	Continuing	Continuing
374C: <i>GDF - Medical Combat Support</i>	0.000	0.000	49.661	27.177	0.000	27.177	18.372	22.919	18.078	18.418	Continuing	Continuing
374D: <i>GDF - Restoration &amp; Healthcare Systems</i>	0.000	0.000	26.731	26.078	0.000	26.078	24.726	32.595	36.502	37.232	Continuing	Continuing
374E: <i>GDF - Medical Materiel/ Medical Biological Defense Equipment Development</i>	0.000	0.000	0.000	21.863	0.000	21.863	24.289	24.473	25.075	25.327	Continuing	Continuing
434A: <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>	12.000	4.080	4.162	4.245	0.000	4.245	4.331	4.417	4.505	4.595	Continuing	Continuing
441: <i>CSI- Joint Warfighter Medical Research</i>	0.000	9.234	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**

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 2023 Defense Health Agency **Date:** April 2022

<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 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
Previous President's Budget	149.831	142.252	166.960	0.000	166.960
Current President's Budget	149.831	197.360	166.960	0.000	166.960
Total Adjustments	0.000	55.108	0.000	0.000	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	55.108			
• 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: 464 - *GDF - Restore Core Research Funding Reduction*

Congressional Add: 464 - *USUHS - Restore Core Research Funding Reduction for National Disaster Medical System Pilot Study*

Congressional Add: 400Z - *Congressional Add - Joint civilian-medical surge facility*

Congressional Add Subtotals for Project: 400Z

**Project: 374E: GDF - Medical Materiel/Medical Biological Defense Equipment Development**

Congressional Add: *GDF MPSACD Medical Materiel/Medical Biological Defense Equipment Development*

Congressional Add Subtotals for Project: 374E

	<b>FY 2021</b>	<b>FY 2022</b>
	5.000	16.000
	-	4.500
	-	15.000
	-	14.000
	5.000	49.500
	0.000	0.000
	0.000	0.000

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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2023 Defense Health Agency **Date:** April 2022

<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>Medical Products Support and Advanced Concept Development</i>
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**Congressional Add Details (\$ in Millions, and Includes General Reductions)**

	<b>FY 2021</b>	<b>FY 2022</b>
Congressional Add Totals for all Projects	5.000	49.500

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency										<b>Date:</b> April 2022		
<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> 400Z / CSI - Congressional Special Interests			
<b>COST (\$ in Millions)</b>	<b>Prior Years (+)</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
400Z: CSI - Congressional Special Interests	401.343	5.000	49.500	0.000	0.000	0.000	0.000	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 2022 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 2021</b>	<b>FY 2022</b>
<b>Congressional Add:</b> 441A - Joint Warfighter Medical Research Program	5.000	16.000
<b>FY 2021 Accomplishments:</b> CSI Add		
<b>FY 2022 Plans:</b> CSI Add		
<b>Congressional Add:</b> 464 - GDF - Restore Core Research Funding Reduction	-	4.500
<b>FY 2022 Plans:</b> This is a program increase due to GDF restoral in the FY22 enacted budget.		
<b>Congressional Add:</b> 464 - USUHS - Restore Core Research Funding Reduction for National Disaster Medical System Pilot Study	-	15.000
<b>FY 2022 Plans:</b> This is a program increase due to restoral in the FY22 enacted budget.		
<b>Congressional Add:</b> 400Z - Congressional Add - Joint civilian-medical surge facility	-	14.000
<b>FY 2022 Plans:</b> FY22 Congressional Add		
<b>Congressional Adds Subtotals</b>	5.000	49.500

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

N/A

**Remarks**

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency		<b>Date:</b> April 2022
<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>

**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>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> 374 / GDF - Medical Products Support and Advanced Concept Development			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
374: GDF - Medical Products Support and Advanced Concept Development	332.623	131.517	0.000	0.000	0.000	0.000	0.000	0.000	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 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
<b>Title:</b> GDF – Medical Product Support and Advanced Concept Development	131.517	0.000	0.000	0.000	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 2022 Plans:</b> Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.					
<b>FY 2023 Base Plans:</b> Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.					
<b>FY 2023 OCO Plans:</b> N/A					
<b>FY 2022 to FY 2023 Increase/Decrease Statement:</b>					

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency	<b>Date:</b> April 2022
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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> 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i>
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.					
<b>Accomplishments/Planned Programs Subtotals</b>	131.517	0.000	0.000	0.000	0.000

**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.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2023 Defense Health Agency **Date:** April 2022

<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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
374A: GDF - Medical Simulation and Training	0.000	0.000	18.490	18.440	0.000	18.440	17.470	16.460	17.020	17.360	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 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
<b>Title:</b> GDF - Medical Simulation and Training	0.000	18.490	18.440	0.000	18.440
<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 Virtual Education Center advances and addresses patient education shortfalls to increase patient experiences and knowledge. 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</p>					

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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>

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
maximize the training simulations, manikins, and will unify patient and clinical education across the MHS and improving healthcare across the Department of Defense.  <b>FY 2023 Base Plans:</b> FY 2023 plans continue efforts as outlined in FY 2022 and support advanced development, prototypes and evaluation of medical simulation and training.  <b>FY 2023 OCO Plans:</b> N/A  <b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Funding increase due to inflation.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	18.490	18.440	0.000	18.440

<b>C. Other Program Funding Summary (\$ in Millions)</b> N/A  <b>Remarks</b>  <b>D. Acquisition Strategy</b> 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 2023 Defense Health Agency										<b>Date:</b> April 2022		
<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 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
374B: GDF - Medical Readiness	0.000	0.000	48.816	69.157	0.000	69.157	83.101	74.568	77.893	79.452	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 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
<b>Title:</b> GDF - Medical Readiness	0.000	48.816	69.157	0.000	69.157
<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. Significant FY22 Programs: the interoperable Medical Automated Systems (iMAS) program plans to develop a Proof of Concept demonstration; the Broad Spectrum Snake Bite Antidote (BSSA) program plans to initiate the Phase 2 clinical trials; the Enterotoxigenic E. coli Vaccine program will initiate Phase 3 clinical trials; the Pharmaceutical Intervention for Noise-Induced Hearing Loss-Acute Exposure Treatment (PINIHL-AET) program plans to work towards Institutional Review Board (IRB) and Human Research Protection Official (HRPO) approvals; and the Health Readiness and Performance System (HRAPS) program plans to begin User Testing and Operational Assessment of its platform. Also, efforts will continue for the following programs: Concussion Dosimetry; Hyperbaric Neurocognitive Assessment System (HNAS); Breath Test for Pulmonary Oxygen Toxicity; Additive					

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency	<b>Date:</b> April 2022
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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> 374B / <i>GDF - Medical Readiness</i>
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Manufacturing Working Group; and Next Generation Environmental Health Risk Management Capabilities program  <b>FY 2023 Base Plans:</b> FY 2023 plans continue efforts as outlined in FY 2022 and support advanced development, prototypes and evaluation of medical readiness capabilities.  <b>FY 2023 OCO Plans:</b> N/A  <b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Increase due to strategic realignments within PE from Medical Combat Support.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	48.816	69.157	0.000	69.157

**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.

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**Exhibit R-2A, RDT&E Project Justification:** PB 2023 Defense Health Agency **Date:** April 2022

<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> 374C / GDF - Medical Combat Support
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
374C: GDF - Medical Combat Support	0.000	0.000	49.661	27.177	0.000	27.177	18.372	22.919	18.078	18.418	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)**

**Title:** GDF - Medical Combat Support

**Description:** 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.

**FY 2022 Plans:**

Programs will focus on operational support. Significant FY22 Programs: Battlefield Pain Management – Ketamine plans to conduct clinical trials; Non-Compressible Hemorrhage Control (NHC) plans for a Milestone B decision for its polymeric foam product; Cold Stored Platelets (CSP) plans for a Milestone B decision and the initiation of a characterization study for In vitro CSP; Canine Blood Products program plans to complete a clinical trauma study; and the Joint Multi-Channel Infusion Pump program plans to achieve compliance with all Milestone B requirements. Also, efforts will continue for the following programs: Hemorrhage Detection (HD) (AMM Monitoring); Traumatic Brain Injury (TBI) Assessment & Diagnosis – Mobile Applications; Rapid Donor Screening; Combat Wound Treatment and Management; Digital Radiography; and Wound Healing Gauze.

**FY 2023 Base Plans:**

	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
<b>Title:</b> GDF - Medical Combat Support	0.000	49.661	27.177	0.000	27.177

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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
FY 2023 plans continue efforts as outlined in FY 2022 and support advanced development, prototypes and evaluation of medical combat support capabilities  <b>FY 2023 OCO Plans:</b> N/A  <b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Decrease due to strategic realignments within PE to Medical Readiness.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	49.661	27.177	0.000	27.177

**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.

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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> 374D / <i>GDF - Restoration &amp; Healthcare Systems</i>
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
374D: <i>GDF - Restoration &amp; Healthcare Systems</i>	0.000	0.000	26.731	26.078	0.000	26.078	24.726	32.595	36.502	37.232	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)**

**Title:** GDF - Restoration & Healthcare Systems

**Description:** 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.

***FY 2022 Plans:***

Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. Significant FY22 Programs: The Traumatic Brain Injury (TBI) - Drug Treatment program will begin moderate TBI Phase 2 adaptive trial enrollment testing for 3 generic drugs (FDA approved for other diseases) as candidates for TBI treatment; The Post Traumatic Stress Disorder (PTSD) - Drug Treatment program will continue the Adaptive Platform Trial (APT) and study to de-risk endpoint selection; and the Bacteriophage for Treatment of Bacterial Infections (BTBI) program plans to complete Phase 1b/2a clinical trials for precision phage mixture. Also, efforts continue for the Post Traumatic Stress Disorder (PTSD) Screening Tool program.

***FY 2023 Base Plans:***

	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
<b>Title:</b> GDF - Restoration & Healthcare Systems	0.000	26.731	26.078	0.000	26.078

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency		<b>Date:</b> April 2022
<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>

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
FY 2023 plans continue efforts as outlined in FY 2022 and support advanced development, prototypes and evaluation of medical restoration and healthcare system capabilities.  <b>FY 2023 OCO Plans:</b> N/A  <b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Increase due to inflation program growth.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	26.731	26.078	0.000	26.078

**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 2023 Defense Health Agency **Date:** April 2022

<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> 374E / GDF - Medical Materiel/Medical Biological Defense Equipment Development
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
374E: GDF - Medical Materiel/Medical Biological Defense Equipment Development	0.000	0.000	0.000	21.863	0.000	21.863	24.289	24.473	25.075	25.327	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 Materiel/Medical Biological Defense Equipment Development.

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

	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
<b>Title:</b> GDF MPSACD Medical Materiel/Medical Biological Defense Equipment Development	0.000	0.000	21.863	0.000	21.863
<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 Materiel/Medical Biological Defense Equipment Development from Army PE 0603807A.					
<b>FY 2022 Plans:</b> N/A					
<b>FY 2023 Base Plans:</b> Programs will focus on advanced component development, test and evaluation in support of Medical Materiel/Medical Biological Defense Equipment Development.					
<b>FY 2023 OCO Plans:</b> N/A					
<b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Funding increase for this Project was due to transfer/realignment from Army.					
<b>Accomplishments/Planned Programs Subtotals</b>	0.000	0.000	21.863	0.000	21.863
	<b>FY 2021</b>	<b>FY 2022</b>			
<b>Congressional Add:</b> GDF MPSACD Medical Materiel/Medical Biological Defense Equipment Development	0.000	0.000			

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<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency		<b>Date:</b> April 2022	
<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> 374E / <i>GDF - Medical Materiel/Medical Biological Defense Equipment Development</i>	
		<b>FY 2021</b>	<b>FY 2022</b>
<i>FY 2021 Accomplishments:</i> N/A			
<i>FY 2022 Plans:</i> N/A			
<b>Congressional Adds Subtotals</b>		0.000	0.000

**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 2023 Defense Health Agency										<b>Date:</b> April 2022		
<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> 434A / Air & Space Medical Readiness Advanced Concept Development (AF)			
<b>COST (\$ in Millions)</b>	<b>Prior Years</b>	<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>	<b>FY 2024</b>	<b>FY 2025</b>	<b>FY 2026</b>	<b>FY 2027</b>	<b>Cost To Complete</b>	<b>Total Cost</b>
434A: Air & Space Medical Readiness Advanced Concept Development (AF)	12.000	4.080	4.162	4.245	0.000	4.245	4.331	4.417	4.505	4.595	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)**

**Title:** Air & Space Medical Readiness Advanced Concept Development (AF)

**Description:** 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.

**FY 2022 Plans:**

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 handheld 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).

**FY 2023 Base Plans:**

<b>FY 2021</b>	<b>FY 2022</b>	<b>FY 2023 Base</b>	<b>FY 2023 OCO</b>	<b>FY 2023 Total</b>
4.080	4.162	4.245	0.000	4.245

**UNCLASSIFIED**

<b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2023 Defense Health Agency	<b>Date:</b> April 2022
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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> 434A / <i>Air &amp; Space Medical Readiness Advanced Concept Development (AF)</i>
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<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
FY22 plans continue efforts as outlined in FY 2021.					
<b>FY 2023 OCO Plans:</b> N/A					
<b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Funding increase due to inflation.					
<b>Accomplishments/Planned Programs Subtotals</b>	4.080	4.162	4.245	0.000	4.245

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

N/A

**Remarks**

Accomplishments: Made significant advancements towards the materiel development of the Patient Loading System (PLS) which has now transitioned to production. The PLS is an en route care ramp system for on- / off- boarding with high deck aircraft. Additionally, the Field Intravenous Expeditionary System yielded two prototypes that went early operational assessments prior to Phase III and is being postured for joint acquisition consideration. The Spinal Immobilization Transport Device; Phase III SBIR Mod for final development of four First Article production representative units to be delivered no later than December 2021 followed by Safe-to-Fly and Final Operational Test and Evaluation slated to begin January 2022. The final technical report is slated to be delivered NLT 30 Mar 2022 with a production contract award expected NLT June 2022.

**D. Acquisition Strategy**

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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**Exhibit R-2A, RDT&E Project Justification:** PB 2023 Defense Health Agency **Date:** April 2022

<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> 441 / CSI- Joint Warfighter Medical Research
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
441: CSI- Joint Warfighter Medical Research	0.000	9.234	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**  
Congressional Add In

<b>B. Accomplishments/Planned Programs (\$ in Millions)</b>	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
<b>Title:</b> CSI- Joint Warfighter Medical Research	9.234	0.000	0.000	0.000	0.000
<b>Description:</b> Congressional Add In					
<b>FY 2022 Plans:</b> Congressional Add In					
<b>FY 2023 Base Plans:</b> Congressional Add In					
<b>FY 2023 OCO Plans:</b> N/A					
<b>FY 2022 to FY 2023 Increase/Decrease Statement:</b> Congressional Add In					
<b>Accomplishments/Planned Programs Subtotals</b>	9.234	0.000	0.000	0.000	0.000

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

**Remarks**

**D. Acquisition Strategy**  
N/A