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

Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept 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	437.585	190.750	202.431	172.351	0.000	172.351	175.518	179.161	182.475	186.125	Continuing	Continuing
400Z: <i>CSI - Congressional Special Interests</i>	61.816	53.236	35.640	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>	363.689	0.000	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	18.490	18.422	18.445	0.000	18.445	16.460	17.020	17.360	17.707	Continuing	Continuing
374B: <i>GDF - Medical Readiness</i>	0.000	49.534	69.087	71.227	0.000	71.227	74.568	77.893	79.452	81.041	Continuing	Continuing
374C: <i>GDF - Medical Combat Support</i>	0.000	43.453	27.150	27.917	0.000	27.917	22.919	18.078	18.418	18.786	Continuing	Continuing
374D: <i>GDF - Restoration & Healthcare Systems</i>	0.000	22.027	26.052	26.080	0.000	26.080	32.595	36.502	37.232	37.977	Continuing	Continuing
374E: <i>GDF - Medical Materiel/ Medical Biological Defense Equipment Development</i>	0.000	0.000	21.835	24.352	0.000	24.352	24.559	25.163	25.417	25.926	Continuing	Continuing
434A: <i>Air & Space Medical Readiness Advanced Concept Development (AF)</i>	12.080	4.010	4.245	4.330	0.000	4.330	4.417	4.505	4.596	4.688	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 military operational users; prototyping; risk reduction and product transition efforts for medical devices and/or 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.

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. Research 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 DoD strategic framework documents.

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Appropriation/Budget Activity 0130: <i>Defense Health Program I BA 2: RDT&E</i>	R-1 Program Element (Number/Name) PE 0604110DHA I <i>Medical Products Support and Advanced Concept Development</i>
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Program development and execution is coordinated with all of the Military Service Components and the 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 joint medical materiel development efforts and of Service Authorities for Service-specific capability requirements. As technologies mature, the most promising efforts will transition to medical products and support systems development funding, PE 0605145.

B. Program Change Summary (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Previous President's Budget	142.252	166.960	172.351	0.000	172.351
Current President's Budget	190.750	202.431	172.351	0.000	172.351
Total Adjustments	48.498	35.471	0.000	0.000	0.000
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-0.169			
• Congressional Rescissions	-	-			
• Congressional Adds	55.108	35.640			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-	-			
• SBIR/STTR Transfer	-6.610	-			

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

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

- Congressional Add: 374 - *Congressional Add - GDF - Medical Products Support and Advanced Concept Development*
- 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: 554 - *Joint Civilian Medical Surge Facility*

Congressional Add Subtotals for Project: 400Z

Congressional Add Totals for all Projects

	FY 2022	FY 2023
	5.404	0.000
	15.466	16.000
	4.336	0.000
	14.486	0.000
	13.544	19.640
	53.236	35.640
	53.236	35.640

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency										Date: March 2023		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development			Project (Number/Name) 400Z / CSI - Congressional Special Interests				
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
400Z: CSI - Congressional Special Interests	61.816	53.236	35.640	0.000	0.000	0.000	0.000	0.000	0.000	0.000	Continuing	Continuing

A. Mission Description and Budget Item Justification

Defense Health Program funded Congressional Special Interest (CSI) directed research. The strategy for the FY 2023 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)

	FY 2022	FY 2023
Congressional Add: 374 - Congressional Add - GDF - Medical Products Support and Advanced Concept Development <i>FY 2022 Accomplishments:</i> FY22 Congressional Add <i>FY 2023 Plans:</i> N/A	5.404	0.000
Congressional Add: 441A - Joint Warfighter Medical Research Program <i>FY 2022 Accomplishments:</i> FY22 Congressional Add <i>FY 2023 Plans:</i> FY23 Congressional Add	15.466	16.000
Congressional Add: 464 - GDF - Restore Core Research Funding Reduction <i>FY 2022 Accomplishments:</i> This is a program increase due to GDF restoral in the FY22 enacted budget. <i>FY 2023 Plans:</i> N/A	4.336	0.000
Congressional Add: 464 - USUHS - Restore Core Research Funding Reduction for National Disaster Medical System Pilot Study <i>FY 2022 Accomplishments:</i> This is a program increase due to restoral in the FY22 enacted budget. <i>FY 2023 Plans:</i> N/A	14.486	0.000
Congressional Add: 554 - Joint Civilian Medical Surge Facility <i>FY 2022 Accomplishments:</i> FY22 Congressional Add <i>FY 2023 Plans:</i> FY23 Congressional Add	13.544	19.640
Congressional Adds Subtotals	53.236	35.640

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency		Date: March 2023
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 400Z / <i>CSI - Congressional Special Interests</i>

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

N/A

Remarks

N/A

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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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency										Date: March 2023		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development				Project (Number/Name) 374 / GDF - Medical Products Support and Advanced Concept Development			
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
374: GDF - Medical Products Support and Advanced Concept Development	363.689	0.000	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)

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: GDF – Medical Product Support and Advanced Concept Development	0.000	0.000	0.000	0.000	0.000
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 and medical training systems technologies.					
FY 2023 Plans: Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.					
FY 2024 Base Plans: N/A					
FY 2024 OCO Plans: N/A					
FY 2023 to FY 2024 Increase/Decrease Statement:					

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency	Date: March 2023
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374 / <i>GDF - Medical Products Support and Advanced Concept Development</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Starting in FY 2022, funding from Project 374 was realigned to Projects 374A, 374B, 374C, and 374D.					
Accomplishments/Planned Programs Subtotals	0.000	0.000	0.000	0.000	0.000

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

N/A

Remarks

N/A

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 2024 Defense Health Agency **Date:** March 2023

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development	Project (Number/Name) 374A / 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
374A: GDF - Medical Simulation and Training	0.000	18.490	18.422	18.445	0.000	18.445	16.460	17.020	17.360	17.707	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)

Title: GDF - Medical Simulation and Training

Description: 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.

FY 2023 Plans:

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

FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
18.490	18.422	18.445	0.000	18.445

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>maximize the training simulations, manikins, and will unify patient and clinical education across the MHS and improving healthcare across the Department of Defense.</p> <p>FY 2024 Base Plans: FY 2024 plans continue efforts as outlined in FY 2023 and support advanced development, prototypes and evaluation of medical simulation and training.</p> <p>FY 2024 OCO Plans: N/A</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to inflation.</p>					
Accomplishments/Planned Programs Subtotals	18.490	18.422	18.445	0.000	18.445

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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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency										Date: March 2023		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 374B / <i>GDF - Medical Readiness</i>			
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
374B: <i>GDF - Medical Readiness</i>	0.000	49.534	69.087	71.227	0.000	71.227	74.568	77.893	79.452	81.041	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)

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: GDF - Medical Readiness	49.534	69.087	71.227	0.000	71.227
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 2023 Plans:					
Programs will focus on prevention of illness and injury along with optimization of human performance. Significant FY23 Programs: Canine Thermal Model and Monitor (CTMM) plans to perform Cyber, IV&V, and Operational Assessment Tests for Increment 2; Health Readiness and Performance System (HRAPS) plans to transition wearable system programs under its integrated system; Transition to Joint Health Risk Management to HRAPS and inclusion of wearable noise; COVID-19 pilot study using algorithms developed to provide early warning of COVID-19 infection; and MASTR-E transition for Squad Performance Prediction algorithms and MOMRP/USARIEM for compression shirt technology. Completion of Broad-Spectrum Snake Bite Antidote First Phase 2 clinical trial and initiation of second Phase 2 clinical trial and registration batch manufacturing; and Pharmaceutical Intervention for Noise-Induced Hearing Loss - Acute Exposure Treatment (PINIHL-AET) will					

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

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
continue ongoing Phase 2 clinical trials to test safety and efficacy of a promising pharmaceutical. Also, continue development efforts for Digital Radiography. FY 2024 Base Plans: FY 2024 plans continue efforts as outlined in FY 2023 and support advanced development, prototypes and evaluation of medical readiness capabilities. FY 2024 OCO Plans: N/A FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to inflation.					
Accomplishments/Planned Programs Subtotals	49.534	69.087	71.227	0.000	71.227

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 2024 Defense Health Agency **Date:** March 2023

Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development	Project (Number/Name) 374C / 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
374C: GDF - Medical Combat Support	0.000	43.453	27.150	27.917	0.000	27.917	22.919	18.078	18.418	18.786	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 2023 Plans:

Programs will focus on operational support. The Cold Stored Platelets program will continue ongoing Phase 3 clinical studies as well as ongoing in vitro platelet characterization studies. 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. Plans for a 510(k) FD submission for a product as well as the restart of a clinical trial for another product. Canine Blood Products program plans to continue manufacturing feasibility studies, canine trauma treatment clinical studies; and award a contract for restoration of Oxyglobin production. In addition, efforts will continue for the following programs:

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: GDF - Medical Combat Support	43.453	27.150	27.917	0.000	27.917

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Advanced Medical Monitor (formerly integrated Hemorrhage Detection); TBI Assessment & Diagnosis – Mobile Applications; Autonomous Closed Loop Control/Mechanical Ventilation (ACLC/MV). FY 2024 Base Plans: FY 2024 plans continue efforts as outlined in FY 2023 and support advanced development, prototypes and evaluation of medical combat support capabilities. FY 2024 OCO Plans: N/A FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to inflation.					
Accomplishments/Planned Programs Subtotals	43.453	27.150	27.917	0.000	27.917

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 2024 Defense Health Agency										Date: March 2023		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>				Project (Number/Name) 374D / <i>GDF - Restoration & Healthcare Systems</i>			
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
374D: <i>GDF - Restoration & Healthcare Systems</i>	0.000	22.027	26.052	26.080	0.000	26.080	32.595	36.502	37.232	37.977	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)

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: GDF - Restoration & Healthcare Systems	22.027	26.052	26.080	0.000	26.080
<p>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.</p> <p>FY 2023 Plans: Programs will focus on treatments to be used to restore form and function to warfighters as well as improve healthcare. Joint Multi-Channel Infusion Pump program continue TMRR contract execution and plan for initial and final design review. The Post Traumatic Stress Disorder-Drug Treatment program will continue its CAPS-5 Adaptive Platform enabling study; rolling out its Adaptive Platform Trial; and solicit industry partners for Phase 3 clinical trials. The Traumatic Brain Injury-Drug Treatment program plans an adaptive platform master protocol for Phase 2 Clinical Trials on industry exempt on-market generic oral drugs for moderate TBI; plans to enroll first subjects in Q2 and rolling site initiations across 10 sites; continue development efforts and complete IPRs for</p>					

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
<p>pipeline novel TBI drug developers. Continue efforts for the Post Traumatic Stress Disorder-Screening Tool and Bacteriophage Treatment for Bacterial Infections programs.</p> <p>FY 2024 Base Plans: FY 2024 plans continue efforts as outlined in FY 2023 and support advanced development, prototypes and evaluation of medical restoration and healthcare system capabilities.</p> <p>FY 2024 OCO Plans: N/A</p> <p>FY 2023 to FY 2024 Increase/Decrease Statement: Increase due to inflation.</p>					
Accomplishments/Planned Programs Subtotals	22.027	26.052	26.080	0.000	26.080

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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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development	Project (Number/Name) 374E / GDF - Medical Materiel/Medical Biological Defense Equipment Development
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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
374E: GDF - Medical Materiel/Medical Biological Defense Equipment Development	0.000	0.000	21.835	24.352	0.000	24.352	24.559	25.163	25.417	25.926	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 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: GDF - Medical Materiel/Medical Biological Defense Equipment Development	0.000	21.835	24.352	0.000	24.352
Description: 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. Funding is provided for engineering and manufacturing development of medical devices and blood products in support of enhanced combat casualty care and for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention and treatment to increase medical readiness. This project provides for the advanced product development and prototyping of Army lifesaving medical field systems.					
FY 2023 Plans: Programs will focus on advanced component development, test and evaluation in support of Medical Materiel/Medical Biological Defense Equipment Development.					
FY 2024 Base Plans: Programs will focus on advanced component development, test and evaluation in support of medical materiel/medical biological defense equipment and therapeutics development. Significant FY24 Programs: Temporary Corneal Repair, Burn Treatment Skin Repair, and Rapid Human Diagnostics.					
FY 2024 OCO Plans: N/A					
FY 2023 to FY 2024 Increase/Decrease Statement: Increase supports technology maturation in the area of wound prevention and treatments development.					
Accomplishments/Planned Programs Subtotals	0.000	21.835	24.352	0.000	24.352

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency		Date: March 2023
Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 374E / <i>GDF - Medical Materiel/Medical Biological Defense Equipment 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		
Appropriation/Budget Activity 0130 / 2					R-1 Program Element (Number/Name) PE 0604110DHA / Medical Products Support and Advanced Concept Development				Project (Number/Name) 434A / Air & Space Medical Readiness Advanced Concept Development (AF)			
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
434A: Air & Space Medical Readiness Advanced Concept Development (AF)	12.080	4.010	4.245	4.330	0.000	4.330	4.417	4.505	4.596	4.688	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 advanced development, procurement, fielding, and sustainment. This project enables the fielding of advanced medical capabilities (Technology Readiness Level-TRL 5-8) 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 operational end-users.

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

	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
Title: Air & Space Medical Readiness Advanced Concept Development (AF)	4.010	4.245	4.330	0.000	4.330
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 Technical Maturation and Risk Reduction (TMRR) and Engineering and Manufacturing Development (EMD) for prototypes and production representative units respectively that address AF capability gaps in aerospace and operational medicine and medical readiness.					
FY 2023 Plans: Two to three new materiel efforts are projected for FY23; additionally, three projects are continuing from previous fiscal years focused on restoring blood flow to extremities, hand-held diagnostics, and consolidation of vision testing into a single device. Incoming projects are geared towards closing capability gaps related to hemorrhage control which is the leading cause of mortality in operational environments and total exposure health to mitigate the exposure of our warfighters to hazardous particles and compounds.					
FY 2024 Base Plans: Approximately four new projects are expected to transition to materiel development in FY24 along with funding of follow-on requirements for current projects related to total exposure health. Continued engagement with industry partners to ascertain industry to government opportunities to rapidly facilitate medical products to our Manpower					

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Exhibit R-2A, RDT&E Project Justification: PB 2024 Defense Health Agency	Date: March 2023
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Appropriation/Budget Activity 0130 / 2	R-1 Program Element (Number/Name) PE 0604110DHA / <i>Medical Products Support and Advanced Concept Development</i>	Project (Number/Name) 434A / <i>Air & Space Medical Readiness Advanced Concept Development (AF)</i>
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2022	FY 2023	FY 2024 Base	FY 2024 OCO	FY 2024 Total
and Force Equipment Packaging (MEPFAKs) and Major Commands (MAJCOMs) will continue to expand the portfolio. FY 2024 OCO Plans: N/A FY 2023 to FY 2024 Increase/Decrease Statement: Funding increase due to inflation.					
Accomplishments/Planned Programs Subtotals	4.010	4.245	4.330	0.000	4.330

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

N/A

Remarks

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.