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Exhibit R-2, RDT&E Budget Item Justification: PB 2021 Army **Date:** February 2020

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| Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army / BA 5: System Development & Demonstration (SDD)</i> | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> |
|--|--|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|---|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| Total Program Element | - | 45.054 | 48.264 | 49.870 | - | 49.870 | 46.860 | 49.173 | 46.166 | 47.070 | 0.000 | 332.457 |
| 812: <i>Mil HIV Vac&Drug Dev</i> | - | 1.140 | 1.201 | 1.229 | - | 1.229 | 1.066 | 6.063 | 6.259 | 6.259 | 0.000 | 23.217 |
| 832: <i>Field Medical Systems Engineering Development</i> | - | 33.175 | 31.218 | 32.282 | - | 32.282 | 31.621 | 29.896 | 29.774 | 30.447 | 0.000 | 218.413 |
| 849: <i>Infec Dis Drug/Vacc Ed</i> | - | 10.739 | 15.845 | 16.359 | - | 16.359 | 14.173 | 13.214 | 10.133 | 10.364 | 0.000 | 90.827 |

A. Mission Description and Budget Item Justification

This Program Element (PE) funds advanced development of medical materiel within the System Demonstration and Low Rate Initial Production portions of the acquisition life cycle using 6.5 (System Development and Demonstration) funding. It supports products successfully developed in the Systems Integration portion of the Systems Development and Demonstration phases through completion of the Milestone C Decision Review. Commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use, when available. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the Food and Drug Administration (FDA).

Projects in this PE include the following:

Project 812 funds military relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development focused on military unique needs effecting manning, mobilization, and deployment. Products from this project will normally transition to Department of Defense (DoD) Health Programs or Other Procurement, Army (OPA) Funds.

Project 832 funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Mature COTS medical products are also evaluated for military use. Consideration will also be given to reduce the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. Products from this project will normally transition to OPA Funds.

Project 849 funds development of candidate medical countermeasures for military relevant infectious diseases. These products fall in four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. Products from this project will normally transition to DoD Health Programs or OPA funds.

These Projects are managed by United States (U.S.) Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the U.S. Army Medical Research and Materiel Command.

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| B. Program Change Summary (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget | 44.495 | 48.264 | 49.365 | - | 49.365 |
| Current President's Budget | 45.054 | 48.264 | 49.870 | - | 49.870 |
| Total Adjustments | 0.559 | 0.000 | 0.505 | - | 0.505 |
| • Congressional General Reductions | - | - | | | |
| • Congressional Directed Reductions | - | - | | | |
| • Congressional Rescissions | - | - | | | |
| • Congressional Adds | - | - | | | |
| • Congressional Directed Transfers | - | - | | | |
| • Reprogrammings | 0.559 | - | | | |
| • SBIR/STTR Transfer | - | - | | | |
| • Adjustments to Budget Years | - | - | 0.505 | - | 0.505 |

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| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 812 / <i>Mil HIV Vac&Drug Dev</i> |
|--|--|---|

| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
|--------------------------------------|-------------|---------|---------|--------------|-------------|---------------|---------|---------|---------|---------|------------------|------------|
| 812: <i>Mil HIV Vac&Drug Dev</i> | - | 1.140 | 1.201 | 1.229 | - | 1.229 | 1.066 | 6.063 | 6.259 | 6.259 | 0.000 | 23.217 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project funds militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development is focused on militarily unique needs effecting manning, mobilization, and deployment.

The major contractor is The Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|---------|---------|---------|
| <p>Title: Military HIV Vaccine and Drug Development</p> <p>Description: This effort provides funds for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing of vaccines for medical countermeasures to HIV.</p> <p>FY 2020 Plans: Continue support to Global Vaccine Candidate clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.</p> <p>FY 2021 Plans: Continue support to Global Vaccine Candidate clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: The minor increase of funding in FY 2021 was due to the inflation factor.</p> | 1.140 | 1.146 | 1.229 |
| <p>Title: FY 2020 SBIR/STTR Transfer</p> <p>Description: Funding transferred in accordance with Title 15 USC ?638</p> <p>FY 2020 Plans: Funding transferred in accordance with Title 15 USC ?638</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement:</p> | - | 0.055 | - |

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| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 812 / <i>Mil HIV Vac&Drug Dev</i> |

| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| Funding transferred in accordance with Title 15 USC ?638 | | | |
| Accomplishments/Planned Programs Subtotals | 1.140 | 1.201 | 1.229 |

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

N/A

Remarks

D. Acquisition Strategy

To support testing and evaluation of commercially developed vaccine candidates in government-managed trials.

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army **Date:** February 2020

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| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | Project (Number/Name) 812 / Mil HIV Vac&Drug Dev |
|--|---|--|

| Management Services (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|--------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | | | |
| Medical Product Development Management Services Cost | Various | Various : Various | 2.833 | 0.396 | | 1.146 | | 1.229 | | - | | 1.229 | Continuing | Continuing | - |
| FY 2020 SBIR/STTR Transfer | TBD | Various : Various | - | - | | 0.055 | | - | | - | | - | 0.000 | 0.055 | - |
| Subtotal | | | 2.833 | 0.396 | | 1.201 | | 1.229 | | - | | 1.229 | Continuing | Continuing | N/A |

| Product Development (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|------------------------|--|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | | | |
| Medical Product Development Cost | Various | Henry M. Jackson Foundation, : Various | 33.967 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Subtotal | | | 33.967 | - | | - | | - | | - | | - | Continuing | Continuing | N/A |

| Support (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|---|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | | | |
| Medical Product Development Support Cost | Various | Various : Various | 2.413 | - | | - | | - | | - | | - | Continuing | Continuing | - |
| Regulatory Support | Option/Various | Clinical Research Management, Inc : Various | 0.835 | 0.065 | | - | | - | | - | | - | 0.000 | 0.900 | - |
| Subtotal | | | 3.248 | 0.065 | | - | | - | | - | | - | Continuing | Continuing | N/A |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army | | | | | | | | | | | Date: February 2020 | | | | |
| Appropriation/Budget Activity 2040 / 5 | | | | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | Project (Number/Name) 812 / Mil HIV Vac&Drug Dev | | | | | | | |
| Test and Evaluation (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Medical Product Development T&E Cost | Various | Henry M. Jackson Foundation, : Various | 28.110 | 0.679 | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Subtotal | | | 28.110 | 0.679 | | - | | - | | - | | - | Continuing | Continuing | N/A |
| | | | Prior Years | FY 2019 | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract | |
| Project Cost Totals | | | 68.158 | 1.140 | 1.201 | | 1.229 | | - | | 1.229 | Continuing | Continuing | N/A | |
| Remarks | | | | | | | | | | | | | | | |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army | | | Date: February 2020 |
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| Event Name | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | | FY 2024 | | | | FY 2025 | | | | | | | |
|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|--|--|--|--|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | | | | |
| Global HIV (Ad26/Ad26+gp140) Biologic License Application (BLA) Submission/MS C | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Global HIV (Ad26/Ad26+gp140) BLA Approval | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Global HIV (Ad26/Ad26+gp140) Post FDA Approval Marketing Studies | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Global HIV (Ad26/Ad26+gp140) Fielding | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| Exhibit R-4A, RDT&E Schedule Details: PB 2021 Army | | Date: February 2020 |
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Schedule Details

| Events | Start | | End | |
|---|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Global HIV (Ad26/Ad26+gp140) Biologic License Application (BLA) Submission/MS C | 1 | 2024 | 1 | 2024 |
| Global HIV (Ad26/Ad26+gp140) BLA Approval | 4 | 2024 | 4 | 2024 |
| Global HIV (Ad26/Ad26+gp140) Post FDA Approval Marketing Studies | 1 | 2025 | 4 | 2028 |
| Global HIV (Ad26/Ad26+gp140) Fielding | 1 | 2026 | 4 | 2029 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Army | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 2040 / 5 | | | | | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | | Project (Number/Name) 832 / Field Medical Systems Engineering Development | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 832: Field Medical Systems Engineering Development | - | 33.175 | 31.218 | 32.282 | - | 32.282 | 31.621 | 29.896 | 29.774 | 30.447 | 0.000 | 218.413 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Mature COTS medical products are also evaluated for military use. Specifically funds pivotal (conclusive) human clinical trials or mechanical engineering evaluations for effectiveness of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Consideration is also given to reducing the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. This work is frequently completed through a laboratory/contractor team with the contractor obtaining the U.S. Food and Drug Administration (FDA) licensure for sale of the product.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; Se Qual Technologies, Inc.; Enginivity, Inc.; Ultrasound Diagnostician; HemCon Medical Technologies; Cerdak Ltd; Hemerus Medical, LLC; Fast Track Drugs & Biologics, LLC; Integrated Medical Systems, Inc.; the National Institutes of Health National Heart, Lung and Blood Institute (NHLBI); and the U.S. Army Aeromedical Research Laboratory, Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation. Other military agencies include Program Executive Office (PEO) Soldier, PEO Combat Support/Combat Service Support (CS & CSS), and Naval Undersea Warfare Center.

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

| | FY 2019 | FY 2020 | FY 2021 |
|---|----------------|----------------|----------------|
| <p>Title: Field Medical Systems Engineering Development PM Warfighter Expeditionary Medicine and Treatment (formerly PM Medical Devices)</p> <p>Description: This effort funds the engineering and manufacturing development of medical products for enhanced combat casualty care.</p> <p>FY 2020 Plans: Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Will continue development and testing on a reduced number/fewer types of devices (compared to FY19) to ensure the most current and cost effective devices are being utilized. Equipment will be selected for modernization based on life cycle plan as part of a Sets, Kits and Outfits (SKO).</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding decreased due to PMO reorganization.</p> | 2.946 | 1.788 | - |
| <p>Title: Field Medical Systems Engineering Development PM Warfighter Deployed Medical Systems</p> <p>Description: Funding is provided for development of blood products enhanced combat casualty care and follow-on care.</p> | - | - | 1.676 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| <p>FY 2021 Plans: Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment will be selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: Funding increased due to PMO reorganization.</p> | | | | |
| <p>Title: Field Medical Systems Engineering Development PM Warfighter Protection and Acute Care (formerly PM Pharmaceuticals)</p> <p>Description: Funding is provided for engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including blood products.</p> <p>FY 2020 Plans: Cryopreserved Platelets: Continuing the new acquisition strategy that was developed and implemented in FY 2018 where a single commercial partner is utilized for the manufacturing development, clinical trials and regulatory processes thru licensure. Continue non-clinical in-Vitro characterization and Phase 2 Clinical Trial efficacy study.</p> <p>Freeze-Dried Plasma Program: Will complete the Phase 2 safety and effectiveness study and prepare for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study.</p> <p>FY 2021 Plans: Cryopreserved Platelets: Will continue the new acquisition strategy that was developed and implemented in FY 2018 where a single commercial partner is utilized for the manufacturing development, clinical trials and regulatory processes thru licensure. Will continue non-clinical in-Vitro characterization and Phase 2 Clinical Trial efficacy study.</p> <p>Freeze-Dried Plasma Program: Will complete the Phase 2 safety and effectiveness study and prepare for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: The increase of funding in FY 2021 is due to the planned progression of medical products under development.</p> | | 11.962 | 7.905 | 14.702 |
| <p>Title: Field Medical Systems Engineering Development PM Warfighter Health, Performance and Evacuation (formerly PM Medical Support Systems)</p> <p>Description: This project funds the engineering and manufacturing development of medical products for prevention of injury, enhanced combat casualty care, and evacuation.</p> | | 5.430 | 4.247 | 5.019 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| <p><i>FY 2020 Plans:</i> Modernization of medical equipment sets: Will continue to evaluate the Field Hospital waste water collection system, blood transport products, and other commercial items for medical equipment sets.</p> <p>Airworthiness Testing: Conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation.</p> <p>Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package and CASEVAC: Collaborate with Program Executive Office Combat Support/Combat Service Support for implementation of the CASEVAC system for the Joint Light Tactical Vehicle (JLTV).</p> <p>Waste Treatment System for the CSH: Project was not initiated as planned in FY 2018.</p> <p>Soldier Optimization Decision Aids (SODA): Will transition the Cold Weather Ensemble Decision Aid and the Heat Strain Decision Aid to Program Executive Office Soldier. Will continue to refine the Environment Health Assessment and Risk Management (eHARM) tool for transition.</p> <p>Remote Triage Sensor System: Project was not initiated as planned in FY 2018.</p> <p>Semi-autonomous Casualty Evacuation (CASEVAC) Ground Platform (S-MET): Will collaborate with Program Executive Office Combat Support/Combat Service Support for implementation of the CASEVAC system for the S-MET platform.</p> <p>Next Generation Uniform Repellent/Impregnation: Will conduct operational assessment and integration into PEO Soldier uniform procurement.</p> <p>Litter Transport Shock/Stressor Mitigation System (Formerly: Next Generation Immobilization System): Will assess system for augmentation and inclusion in medical unit assemblages containing litters.</p> <p><i>FY 2021 Plans:</i> Modernization of medical equipment sets: Will complete modernization and evaluation of the Field Hospital water distribution and waste water management system and blood transport products. Will continue evaluation of other commercial items for medical equipment sets.</p> | | | | |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| <p>Airworthiness Testing: Will conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products covering air evacuation.</p> <p>Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package and CASEVAC: Will complete design and evaluation of the CASEVAC system for the JLTV</p> <p>Soldier Optimization Decision Aids (SODA): Will coordinate with PEO Soldier to transition the Mental Acuity, Environmental Exposure Electronic (E3) form (formerly Environment Health Assessment and Risk Management (EHARM) tool) and the Cold Weather Ensemble Decision Aid.</p> <p>Next Generation Uniform Repellent/Impregnation: Will complete project and transition to PEO Soldier.</p> <p>Litter Transport Shock/Stressor Mitigation System (Formerly: Next Generation Immobilization System): Project concluded in FY 2018 with transition to the Air Force.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: The increase of funding in FY 2021 is due to projected requirements of the program.</p> | | | | |
| <p>Title: Field Medical Systems Engineering Development - PM Warfighter Brain Health (formerly PM Neurotrauma & Psychological Health)</p> <p>Description: This effort funds systems engineering development of medical products for enhanced combat casualty care for diagnosis of Traumatic Brain Injury (TBI).</p> <p>FY 2020 Plans: Laboratory Assay for Traumatic Brain Injury (TBI) - Point of Care (formerly TBI Diagnostic Assay System): Will conduct required validation studies for testing of a blood assay on the Point of Care Device to aid in the diagnosis of TBI. Will prepare for a submission of the assay for Food and Drug Administration Approval. Will start analysis of data to validate how the assay predicts recovery from TBI.</p> <p>FY 2021 Plans: Laboratory Assay for TBI - Point of Care (formerly TBI Diagnostic Assay System): Will continue validation studies for testing of a blood assay to aid in the diagnosis of TBI. Will finalize FDA submission of the assay for Food and Drug Administration approval. Will finalize data analysis and report on the assay's ability to predict recovery from TBI.</p> | | 12.837 | 16.031 | 10.885 |

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| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| Non-invasive neuro assessment device (NINAD): Moved to WBH due to PMO Reorganization. Will initiate developmental testing and initial operational assessments based on FDA approval and maturity of other commercially available products. FY 2020 to FY 2021 Increase/Decrease Statement: Funding decrease from FY 2020 to FY 2021 due to less funding required for product in FY 2021. | | | | |
| Title: FY 2020 SBIR/STTR Transfer Description: Funding transferred in accordance with Title 15 USC ?638 FY 2020 Plans: Funding transferred in accordance with Title 15 USC ?638 FY 2020 to FY 2021 Increase/Decrease Statement: Funding transferred in accordance with Title 15 USC ?638 | | - | 1.247 | - |
| Accomplishments/Planned Programs Subtotals | | 33.175 | 31.218 | 32.282 |
| C. Other Program Funding Summary (\$ in Millions) N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy To support developing in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding. | | | | |

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Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army **Date:** February 2020

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|--|---|---|

| Management Services (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|--|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | | | |
| Medical Product Development Management Services Cost | Various | Various : Various | 37.734 | 7.511 | | 5.314 | | 6.336 | | - | | 6.336 | Continuing | Continuing | Continuing |
| Medical Product Development Management Services Cost | PO | General Dynamics Information Technology : Frederick MD | - | - | | - | | 0.300 | | - | | 0.300 | 0.000 | 0.300 | - |
| FY 2020 SBIR/STTR Transfer | TBD | Various : Various | - | - | | 1.247 | | - | | - | | - | 0.000 | 1.247 | - |
| Subtotal | | | 37.734 | 7.511 | | 6.561 | | 6.636 | | - | | 6.636 | Continuing | Continuing | N/A |

| Product Development (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | Cost To Complete | Total Cost | Target Value of Contract |
|---|------------------------|---|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | | | |
| Hypertonic Saline Dextran | Various | National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI) : Various | 15.100 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Medical Product Development Cost | Various | Various : Various | 8.576 | 2.352 | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Extended Life Red Blood Cell Product | Various | Hemerus Medical, LLC, : Various | 3.140 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Cryopreserved Platelets | Various | Clinical Research Management, Inc : Hinckley, OH | 6.890 | 2.523 | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Cryopreserved Platelets | Various | TBD : TBD | 1.875 | - | | 2.474 | | 4.250 | | - | | 4.250 | 0.000 | 8.599 | - |
| Intracellular Hemorrhage Treatment | TBD | TBD : TBD | 0.600 | - | | - | | - | | - | | - | 0.000 | 0.600 | - |
| TBI Diagnostic Assay System - Increment II (benchtop/POC) | Various | Banyan BioMarkers, Inc : Alachua, FL | 0.373 | - | | - | | - | | - | | - | 0.000 | 0.373 | - |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army | | | | | | | | | | | | Date: February 2020 | | | |
|--|------------------------|--|-------------|---|------------|---------|------------|---|------------|-------------|------------|---------------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity 2040 / 5 | | | | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | Project (Number/Name) 832 / Field Medical Systems Engineering Development | | | | | | | |
| Product Development (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Noninvasive Neurodiagnostics | TBD | TBD : TBD | 2.647 | - | | - | | - | | - | | - | 0.000 | 2.647 | - |
| Impedance Threshold Device for the Treatment of Traumatic Brain Injury | TBD | Advance Circulatory Systems Inc. : Roseville, MN | 4.387 | - | | - | | - | | - | | - | 0.000 | 4.387 | - |
| Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine) | TBD | TBD : TBD | 6.321 | - | | - | | - | | - | | - | 0.000 | 6.321 | - |
| Advanced wound care | Various | TBD : TBD | 1.230 | - | | - | | - | | - | | - | 0.000 | 1.230 | - |
| Junction Noncompressible Hemorrhage | TBD | RevMedX Inc : Wilsonville OR | 1.805 | - | | - | | - | | - | | - | 0.000 | 1.805 | - |
| Laboratory Assay for Traumatic Brain Injury | C/Various | Abbott Laboratories : Chicago, IL | 2.810 | 10.401 | | 15.996 | | 7.660 | | - | | 7.660 | Continuing | Continuing | Continuing |
| Freeze Dried Plasma | TBD | TBD : TBD | - | 1.437 | | - | | - | | - | | - | 0.000 | 1.437 | - |
| Subtotal | | | 55.754 | 16.713 | | 18.470 | | 11.910 | | - | | 11.910 | Continuing | Continuing | N/A |
| Support (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Regulatory Support | Various | Clinical Research Management, Inc., : Various | 8.350 | 0.410 | | 0.074 | | - | | - | | - | Continuing | Continuing | Continuing |
| Medical Product Development Support Cost | Various | Various : Various | 11.729 | - | | - | | 0.730 | | - | | 0.730 | Continuing | Continuing | Continuing |
| Medical Equipment Sets Development | Various | Various : Various | 2.670 | - | | - | | 1.457 | | - | | 1.457 | 0.000 | 4.127 | - |
| Subtotal | | | 22.749 | 0.410 | | 0.074 | | 2.187 | | - | | 2.187 | Continuing | Continuing | N/A |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army | | Date: February 2020 |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i> |

| Event Name | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | | FY 2024 | | | | FY 2025 | | | |
|---|---------------------------------|---|---|---|------------------------|---|---|---|-------------------------|---|---|---|---|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Transport Telemedicine Systems (TTS)- MEDHUB Platform | [Redacted] | | | | [Redacted] | | | | | | | | | | | | | | | | | | | | | | | |
| | MEDHUB Platform | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Transport Telemedicine Systems (TTS)- MEDHUB Drug Safety & Tracking | [Redacted] | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | MEDHUB Drug Safety and Tracking | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Extremity Injury Repair - Vascular- Pivotal Study | | | | | | | | | [Redacted] | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | Vascular- Pivotal Study | | | | | | | | | | | | | | | | | | | |
| Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing | | | | | | | | | | | | | [Redacted] | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | Vascular- Environmental Testing/Operational Testing | | | | | | | | | | | | | | | |
| Extracorporeal Life Support- Developmental Contract | | | | | [Redacted] | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | Developmental Contract | | | | | | | | | | | | | | | | | | | | | | | |

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| Exhibit R-4A, RDT&E Schedule Details: PB 2021 Army | | Date: February 2020 |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i> |

Schedule Details

| Events | Start | | End | |
|---|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies | 3 | 2017 | 4 | 2020 |
| Cryopreserved Platelets (CPP) Phase III clinical studies | 4 | 2020 | 3 | 2023 |
| Cryopreserved Platelets (CPP) Milestone C | 4 | 2023 | 4 | 2023 |
| Freeze-dried Plasma (FDP) Phase I safety clinical studies | 3 | 2014 | 2 | 2018 |
| FDP Phase 2 efficacy clinical studies | 2 | 2016 | 2 | 2019 |
| FDP MS-B | 3 | 2016 | 3 | 2016 |
| FDP MS-C | 4 | 2020 | 4 | 2020 |
| Noninvasive Neuroassessment Device Development | 1 | 2018 | 1 | 2025 |
| Laboratory Assay for TBI Increment !! Point of Care Device Clinical Trial | 1 | 2020 | 4 | 2022 |
| Laboratory Assay for TBI Point of Care Device MS C Inc 1 | 4 | 2020 | 4 | 2020 |
| Laboratory Assay for TBI Point of Care Device MS C Inc 2 | 4 | 2022 | 4 | 2022 |
| Temporary Corneal Repair | 4 | 2016 | 1 | 2023 |
| Extracorporeal Life Support | 4 | 2016 | 4 | 2024 |
| Temporary Corneal Repair -Prototype Testing | 2 | 2018 | 1 | 2020 |
| Temporary Corneal Repair- Clinical Study | 1 | 2021 | 3 | 2022 |
| Transport Telemedicine Systems (TTS)- MEDHUB Platform | 3 | 2013 | 3 | 2020 |
| Transport Telemedicine Systems (TTS)- MEDHUB Drug Safety and Tracking | 4 | 2017 | 3 | 2024 |
| Extremity Injury Repair - Vascular- Pivotal Study | 1 | 2018 | 1 | 2022 |
| Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing | 1 | 2021 | 1 | 2023 |
| Extracorporeal Life Support- Developmental Contract | 4 | 2019 | 4 | 2021 |

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|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|----------------------------|-------------------------|-------------------|
| Exhibit R-2A, RDT&E Project Justification: PB 2021 Army | | | | | | | | | | Date: February 2020 | | |
| Appropriation/Budget Activity 2040 / 5 | | | | | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | | | | Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2019 | FY 2020 | FY 2021 Base | FY 2021 OCO | FY 2021 Total | FY 2022 | FY 2023 | FY 2024 | FY 2025 | Cost To Complete | Total Cost |
| 849: <i>Infec Dis Drug/Vacc Ed</i> | - | 10.739 | 15.845 | 16.359 | - | 16.359 | 14.173 | 13.214 | 10.133 | 10.364 | 0.000 | 90.827 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project funds development of candidate medical countermeasures (MCM: e.g., vaccines, drugs, diagnostic kits/devices) for militarily relevant infectious diseases. This also funds methods to determine if insects are infected with pathogenic organisms thereby posing a risk to service members' and control insect exposure/prevent Warfighters from being bitten by those insects. It funds research that supports conclusive human clinical trials to demonstrate MCM effectiveness safety and related manufacturing tests. This work, which is jointly performed by military laboratories, civilian contracted pharmaceutical firms and foreign research partners, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. Medical products approved for human use must meet the U.S. Food and Drug Administration (FDA) approval before MCM can be used on Warfighters. Development priority is based upon four major factors: (1) the extent of the disease within the Combatant Commands' theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development, production, and sustainment). Malaria, dysentery, hepatitis, and Dengue diseases (a severe debilitating disease transmitted by mosquitoes), which are found in all Combatant Command areas and are at the top of the infectious diseases risks list.

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

| | FY 2019 | FY 2020 | FY 2021 |
|--|----------------|----------------|----------------|
| Title: Infectious Disease Drug and Vaccine Engineering Development | 10.739 | 15.240 | 16.359 |
| Description: Funding for research and development efforts for drugs and vaccines for infectious diseases that are top threats to deployed US forces. Funds research that supports conclusive human clinical trials to demonstrate effectiveness, safety and related manufacturing tests. | | | |
| FY 2020 Plans: Dengue Tetravalent Vaccine (DTV): Will continue to fund support for Advance Development (AD) candidate vaccine as it enters third year of pivotal phase 3 clinical trial. Malaria Chemoprophylaxis ?Tafenoquine (formerly Next Generation Malaria Prophylaxis): Will continue the retinal (eye) safety study started in FY 2017. Will address any FDA post-marketing approval requirements. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Will conduct safety and therapeutic dose non clinical testing based on FDA guidance. Antimalarial Drug, Artesunate Intravenous: Will conduct required non-clinical study for FDA review. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Army | | Date: February 2020 | | |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| <p>Dengue Vaccine Block II: Will continue the development, testing and selection of strains for the dengue human infection model (DHIM) to be used in the early evaluation of dengue vaccine candidates in advance of phase 2 and 3 trials under PE 0603807A, Project 808.</p> <p>Rapid Diagnostic and Detection Devices (Formerly Infectious Disease Diagnostics (Multiple)): The dengue and chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for dengue and clinical sites identified for chikungunya.</p> <p>Tick-Bourne Encephalitis Vaccine: Develop Pfizer's European Medicines Agency approved TBEVV for FDA licensure following commercial partner agreement</p> <p>FY 2021 Plans: Dengue Vaccine Effort: Will continue to fund support for Advance Development (AD) candidate vaccine for the expanded FDA safety/effectiveness/dosing study in humans.</p> <p>Malaria Prophylactic Drug ? Tafenoquine (TQ) (Formerly Next Generation Malaria Prophylaxis): Achieved MS C in FY19. Will address any remaining FDA post-marketing approval requirements.</p> <p>Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Project terminated in FY 2019.</p> <p>Rapid Diagnostic and Detection Devices: The dengue and chikungunya assays will continue to be developed and evaluated. Clinical testing for dengue will continue.</p> <p>Tick-Bourne Encephalitis Vaccine (TBEVV): Develop Pfizer's European Medicines Agency approved TBEVV for FDA licensure following commercial partner agreement.</p> <p>FY 2020 to FY 2021 Increase/Decrease Statement: The increase of funding in FY 2021 is due to the planned progression of multiple infectious disease medical products in development. Funding will support the FDA requirements for manufacturing development and clinical trials for those products.</p> | | | | |
| <p>Title: FY 2020 SBIR/STTR Transfer</p> <p>Description: Funding transferred in accordance with Title 15 USC ?638</p> <p>FY 2020 Plans:</p> | | - | 0.605 | - |

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| Exhibit R-2A, RDT&E Project Justification: PB 2021 Army | | Date: February 2020 | | |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2019 | FY 2020 | FY 2021 |
| Funding transferred in accordance with Title 15 USC ?638 | | | | |
| FY 2020 to FY 2021 Increase/Decrease Statement: | | | | |
| Funding transferred in accordance with Title 15 USC ?638 | | | | |
| Accomplishments/Planned Programs Subtotals | | 10.739 | 15.845 | 16.359 |
| C. Other Program Funding Summary (\$ in Millions) | | | | |
| N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy | | | | |
| To support testing and evaluation of in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration. | | | | |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army | | | | | | | | | | | | Date: February 2020 | | | |
|--|------------------------|--|-------------|---|------------|---------|------------|---|------------|-------------|------------|---------------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity 2040 / 5 | | | | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed | | | | | | | |
| Management Services (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Medical Product Development Management Services Cost | Various | Various : Various | 21.739 | 3.620 | | 0.737 | | 0.500 | | - | | 0.500 | Continuing | Continuing | Continuing |
| Medical Product Development Management Services Cost | C/CPFF | General Dynamics Information Technology : Frederick MD | 10.885 | 1.586 | | 2.240 | | 1.500 | | - | | 1.500 | 0.000 | 16.211 | - |
| FY 2020 SBIR/STTR Transfer | TBD | Various : Various | - | - | | 0.605 | | - | | - | | - | 0.000 | 0.605 | - |
| Subtotal | | | 32.624 | 5.206 | | 3.582 | | 2.000 | | - | | 2.000 | Continuing | Continuing | N/A |
| Product Development (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Medical Product Development Cost | Various | Various : Various | 38.518 | 1.039 | | 3.460 | | - | | - | | - | Continuing | Continuing | Continuing |
| Topical Antileishmanial Drug | TBD | TBD : TBD | 2.400 | - | | 2.347 | | - | | - | | - | 0.000 | 4.747 | - |
| Topical Antileishmanial Drug | C/TBD | Advantar Laboratories, INC : TBD | 2.686 | - | | 0.797 | | - | | - | | - | 0.000 | 3.483 | - |
| Dengue Tetravalent Vaccine | TBD | TBD : TBD | 2.047 | - | | - | | - | | - | | - | 0.000 | 2.047 | - |
| Rapid Diagnostic and Detection Devices | Various | Inbios, Inc : Seattle WA | - | - | | - | | 3.673 | | - | | 3.673 | 0.000 | 3.673 | - |
| Hemorrhagic Fever W/ Renal Syndrome | C/TBD | TBD : TBD | 1.000 | - | | - | | - | | - | | - | 0.000 | 1.000 | - |
| Subtotal | | | 46.651 | 1.039 | | 6.604 | | 3.673 | | - | | 3.673 | Continuing | Continuing | N/A |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2021 Army | | | | | | | | | | | | Date: February 2020 | | | |
|--|------------------------|---|-------------|---|------------|---------|------------|------------------------------|------------|-------------|------------|---------------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity | | | | R-1 Program Element (Number/Name) | | | | Project (Number/Name) | | | | | | | |
| 2040 / 5 | | | | PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | | | | 849 / Infec Dis Drug/Vacc Ed | | | | | | | |
| Support (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Medical Product Development Support Cost | Various | Various : Various | 19.380 | 0.012 | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Medical Product Development Support Cost | PO | Clinical Research Management, In : Hinckley, OH | 6.383 | 0.055 | | 0.152 | | - | | - | | - | 0.000 | 6.590 | - |
| Subtotal | | | 25.763 | 0.067 | | 0.152 | | - | | - | | - | Continuing | Continuing | N/A |
| Test and Evaluation (\$ in Millions) | | | | FY 2019 | | FY 2020 | | FY 2021 Base | | FY 2021 OCO | | FY 2021 Total | | | |
| Cost Category Item | Contract Method & Type | Performing Activity & Location | Prior Years | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Award Date | Cost | Cost To Complete | Total Cost | Target Value of Contract |
| Medical Product Development T&E Cost | Various | Various : Various | 51.320 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Dengue Tetravalent Vaccine | TBD | WRAIR/AFRIMS : Silver Spring MD | 1.402 | 0.386 | | 0.433 | | 0.390 | | - | | 0.390 | 0.000 | 2.611 | - |
| Dengue Tetravalent Vaccine | C/TBD | BioPath : Philippines | 5.161 | 0.813 | | 2.568 | | 0.750 | | - | | 0.750 | 0.000 | 9.292 | - |
| Product Development of Dengue Tetravalent Vaccine | Various | TBD : TBD | 4.530 | - | | - | | - | | - | | - | 0.000 | 4.530 | - |
| Next Generation Malaria Prophylaxis | Various | DVC : Frederick MD | - | 3.228 | | 2.506 | | 2.729 | | - | | 2.729 | 0.000 | 8.463 | - |
| Tick-Borne Encephalitis Vaccine | Various | TBD : TBD | - | - | | - | | 4.513 | | - | | 4.513 | 0.000 | 4.513 | - |
| Norovirus Vaccine | Various | TBD : TBD | - | - | | - | | 2.304 | | - | | 2.304 | 0.000 | 2.304 | - |
| Subtotal | | | 62.413 | 4.427 | | 5.507 | | 10.686 | | - | | 10.686 | Continuing | Continuing | N/A |
| Project Cost Totals | | | 167.451 | 10.739 | | 15.845 | | 16.359 | | - | | 16.359 | Continuing | Continuing | N/A |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army | | Date: February 2020 |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed |

| Event Name | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | | FY 2024 | | | | FY 2025 | | | |
|--|---------------------------|---|---|---|---------------------|---|---|---|-------------------|---|---|---|------------------------------------|---|---|---|----------------------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials | FY11-FY18 | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review | | | | | | | | | | | | | 5 MS-C | | | | | | | | | | | | | | | |
| DTV Biologic Licensing Application (BLA) Submission | | | | | 2 BLA Submission | | | | | | | | | | | | | | | | | | | | | | | |
| DTV BLA Approval | | | | | | | | | 3 BLA Approval | | | | | | | | | | | | | | | | | | | |
| Rapid Human Diagnostic Devices | | | | | | | | | FY20-FY25 | | | | | | | | | | | | | | | | | | | |
| Norovirus Vaccine Phase 3 Pivotal Clinical Trials | | | | | | | | | | | | | Norovirus Phase 3 Clinical Trials | | | | | | | | | | | | | | | |
| Tick-Borne Encephalitis Vaccine Phase 3 Pivotal Clinical Trials | | | | | | | | | | | | | Tick-Borne Phase 3 Clinical Trials | | | | | | | | | | | | | | | |
| Treatment for Resistant Wound Infections Antifungal Drug Phase 2 safety trial | | | | | | | | | | | | | | | | | Phase 2 safety trial | | | | | | | | | | | |
| Malaria Prophylaxis Post FDA Approval Marketing Studies | Malaria Marketing Studies | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development | | | | | 1 MS-C | | | | | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin TLC New Drug Application (NDA) | | | | | | | | | NDA Submission | | | | | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin TLC FDA Approval | | | | | | | | | | | | | 4 FDA Approval | | | | | | | | | | | | | | | |
| Paromomycin/Gentamicin TLC (Fielding / Delivery) | | | | | | | | | | | | | Fielding/Delivery | | | | | | | | | | | | | | | |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2021 Army | | | Date: February 2020 |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i> | |

| Event Name | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | | FY 2024 | | | | FY 2025 | | | |
|--|--------------------------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 | 1 | 2 | 3 | 4 |
| Leishmania Rapid Diagnostic Device (Fielding / Delivery) | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | Fielding/Delivery | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Hemorrhagic Fever with Renal Syndrome Clinical Studies | Clinical Studies | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dengue Vaccine Block II Adult Indication Studies | Adult Indication Studies | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dengue Vaccine Block II OCONUS Clinical Trials | Clinical Trials | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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| Exhibit R-4A, RDT&E Schedule Details: PB 2021 Army | | Date: February 2020 |
| Appropriation/Budget Activity 2040 / 5 | R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i> |

Schedule Details

| Events | Start | | End | |
|--|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials | 1 | 2011 | 2 | 2020 |
| DTV Phase 2 Adult Traveler / Military Indication Studies | 2 | 2012 | 1 | 2017 |
| DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review | 1 | 2022 | 1 | 2022 |
| DTV Biologic Licensing Application (BLA) Submission | 2 | 2020 | 2 | 2020 |
| DTV BLA Approval | 2 | 2021 | 2 | 2021 |
| Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase | 4 | 2018 | 4 | 2018 |
| Rapid Human Diagnostic Devices | 1 | 2021 | 4 | 2025 |
| Norovirus Vaccine Phase 3 Pivotal Clinical Trials | 3 | 2021 | 4 | 2026 |
| Tick-Borne Encephalitis Vaccine Phase 3 Pivotal Clinical Trials | 2 | 2021 | 4 | 2026 |
| Treatment for Resistant Wound Infections Antifungal Drug Phase 2 safety trial | 2 | 2023 | 4 | 2026 |
| Malaria Prophylaxis Post FDA Approval Marketing Studies | 4 | 2018 | 4 | 2023 |
| Paromomycin/Gentamicin TLC Phase 3 Safety and Effectiveness Clinical Trial | 1 | 2016 | 1 | 2017 |
| Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development | 4 | 2019 | 4 | 2019 |
| Paromomycin/Gentamicin TLC New Drug Application (NDA) | 3 | 2020 | 3 | 2021 |
| Paromomycin/Gentamicin TLC FDA Approval | 4 | 2021 | 4 | 2021 |
| Paromomycin/Gentamicin TLC (Fielding / Delivery) | 4 | 2021 | 4 | 2024 |
| Leishmania Rapid Diagnostic Device (Fielding / Delivery) | 1 | 2015 | 4 | 2020 |
| Hemorrhagic Fever with Renal Syndrome Clinical Studies | 1 | 2016 | 4 | 2020 |
| Dengue Vaccine Block II Adult Indication Studies | 1 | 2016 | 4 | 2020 |
| Dengue Vaccine Block II OCONUS Clinical Trials | 1 | 2016 | 4 | 2020 |