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| Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
|---|-------------|---------|---------|--------------|---|---------------|---------|---------|---------|---------------------|------------------|------------|
| Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army I BA 4: Advanced Component Development & Prototypes (ACD&P) | | | | | R-1 Program Element (Number/Name) PE 0603807A I Medical Systems Advanced Development | | | | | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| Total Program Element | - | 47.336 | 33.491 | 34.284 | - | 34.284 | 39.477 | 40.475 | 43.169 | 35.353 | 0.000 | 273.585 |
| 808: DoD Drug & Vacc Ad | - | 14.382 | 14.372 | 14.004 | - | 14.004 | 16.125 | 16.548 | 16.948 | 17.372 | 0.000 | 109.751 |
| 811: Mil HIV Vac&Drug Dev | - | 4.120 | 5.230 | 5.296 | - | 5.296 | 5.460 | 5.603 | 5.973 | 1.110 | 0.000 | 32.792 |
| 836: Field Medical Systems Advanced Development | - | 17.334 | 13.604 | 14.691 | - | 14.691 | 17.599 | 18.022 | 19.937 | 16.871 | 0.000 | 118.058 |
| CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA) | - | 7.500 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 7.500 |
| FF4: Counterdrug, DDR, Sys Development & Demonstration | - | 4.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 4.000 |
| VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev | - | 0.000 | 0.285 | 0.293 | - | 0.293 | 0.293 | 0.302 | 0.311 | 0.000 | 0.000 | 1.484 |

A. Mission Description and Budget Item Justification

This Program Element (PE) funds development of medical materiel within the early system integration portion of the System Development and Demonstration phase of the acquisition life cycle using 6.4 (Advanced Component Development and Prototype) funding. Program efforts support transition of promising Science and Technology candidate medical technologies (drugs, vaccines, medical devices, diagnostics, and mechanisms for detection and control of disease carrying insects) to larger scale testing in humans for safety and effectiveness. Programs are aligned to meet future force requirements identified within concept documents and organizational structures. This PE also provides funding for Food and Drug Administration (FDA) regulated human clinical trials to gain additional information about safety and effectiveness on the path to licensure for use in humans.

The Projects supported by this PE are:

Project 808 funds development of candidate medical countermeasures for infectious diseases of military relevance. Efforts include vaccines, drugs, diagnostic kits/ devices, and insect control measures. These funds support human clinical efficacy trials of the drug/vaccine in a larger group that are designed to assess performance and to continue safety assessments in a larger group of volunteers. Products from this Project will transition to PE 0604807A/Project 849.

Project 811 funds the development of military relevant human immunodeficiency virus (HIV) medical countermeasures. It provides funding for planning and conducting of human clinical trials in a group of healthy volunteers to assess the drug/vaccine for safety, tolerability, how the drug/vaccine is distributed, metabolized, and excreted from the body, and investigate the appropriate dose for therapeutic use. Products from this Project will transition to PE 0604807A/Project 812.

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Army | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army I BA 4: Advanced Component Development & Prototypes (ACD&P) | | R-1 Program Element (Number/Name) PE 0603807A I Medical Systems Advanced Development | | | | |
| Project 836 funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This project also funds the human clinical trials that test the safety and effectiveness of biologics, devices and demonstration. Clinical trials are conducted in accordance with United States (U.S.) FDA regulations. Products from this project will transition to PE 0604807A/Project 832. | | | | | | |
| Project VS7 funds program upgrades, retrofits, trains, and sustains the fleet of Medical Evacuation legacy helicopters that continue to play a major role in Iraq and Afghanistan. The approved force design increased the number of air frames in the force from 12 to 15 aircraft for 37 medical evacuation (MEDEVAC) companies. All products from this Project will transition to PE 0604807A/Project VS8. | | | | | | |
| Project CS4 funds congressionally special interest in:Transport Telemedicine - Initiate Joint Advanced Technology Demonstration to provide Medical Treatment Facility (MTF) automatic situational awareness system to identify patients en-route to MTFs and automate paramedic tasks. | | | | | | |
| These Projects are managed by 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. | | | | | | |
| Project FF4 funded Secretary of Defense approved counterdrug advanced development efforts used in a major re-design of the Forensic Toxicology Drug Testing Laboratory (FTDTL) information management system used to test urine samples for the presence of illegal drugs. The Drug Testing Program - Client Collection System (DTP-CSS) is comprised of several variations of a desktop application used to select service members for random drug testing, prepare labels for urine specimen bottles, and print corresponding chain-of-custody documents. This Project will standardize DTP-CSS across all services and migrate it to a Web-based system. | | | | | | |
| B. Program Change Summary (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total |
| Previous President's Budget | | 33.503 | 33.491 | 35.572 | - | 35.572 |
| Current President's Budget | | 47.336 | 33.491 | 34.284 | - | 34.284 |
| Total Adjustments | | 13.833 | 0.000 | -1.288 | - | -1.288 |
| • Congressional General Reductions | | -0.015 | - | | | |
| • Congressional Directed Reductions | | - | - | | | |
| • Congressional Rescissions | | - | - | | | |
| • Congressional Adds | | 7.500 | - | | | |
| • Congressional Directed Transfers | | - | - | | | |
| • Reprogrammings | | 3.506 | - | | | |
| • SBIR/STTR Transfer | | -1.158 | - | | | |
| • Adjustments to Budget Years | | - | - | -1.288 | - | -1.288 |
| • OSD Directed Transfer | | 4.000 | - | - | - | - |
| Congressional Add Details (\$ in Millions, and Includes General Reductions) | | | | | FY 2017 | FY 2018 |
| Project: CS4: MEDICAL SYSTEMS ADV DEV INITIATIVES (CA) | | | | | | |

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| Exhibit R-2, RDT&E Budget Item Justification: PB 2019 Army | | Date: February 2018 | |
| Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P) | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | |
| Congressional Add Details (\$ in Millions, and Includes General Reductions) | | FY 2017 | FY 2018 |
| Congressional Add: <i>Congressional Special Interest_ Transport Telemedicine</i> | | 7.500 | - |
| Congressional Add Subtotals for Project: CS4 | | 7.500 | - |
| Congressional Add Totals for all Projects | | 7.500 | - |
| Change Summary Explanation In Fiscal Year 2017 there was a Congressional Add of \$7.5 Million for Medical Systems Advanced Development Initiatives, an Office of the Secretary of Defense (OSD)-directed \$4.0 Million transfer to Project FF4, counterdrug DVR System Development and Demonstration, and there was a reprogramming action of \$3.506 Million from 0604807A/812 to 0603807A/811 for HIV Vaccine Development. | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 808 / DoD Drug & Vacc Ad | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| 808: DoD Drug & Vacc Ad | - | 14.382 | 14.372 | 14.004 | - | 14.004 | 16.125 | 16.548 | 16.948 | 17.372 | 0.000 | 109.751 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification

This Project funds development of candidate medical countermeasures for infectious diseases of military relevance. These efforts are in: vaccines, drugs, diagnostic kits/devices, and to determine if insects are infected with pathogenic organisms capable of infecting service members/preventive medicine measures. These funds support human clinical effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) trials of the drug/vaccine in larger groups that are designed to assess how well the drug/vaccine works, and to continue safety assessments in a larger group of volunteers. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of medical diagnostic kits and devices. This work, which is performed in military laboratories or civilian pharmaceutical firms, is directed toward the prevention of disease, early diagnosis, and accelerated recovery time once diagnosed; to enhance battlefield readiness. All clinical trials are conducted in accordance with United States (U.S.) Food and Drug Administration (FDA) regulations, a mandatory obligation for all military products placed into the hands of medical providers or service members. Product development priorities are determined based upon four major factors: (1) the extent and threat 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 and production).

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

| | FY 2017 | FY 2018 | FY 2019 |
|--|----------------|----------------|----------------|
| Title: DoD Drug and Vaccine Advanced Development | 14.382 | 14.372 | 14.004 |
| Description: Funding is provided for the following effort in the development of candidate medical countermeasures for military relevant infectious disease. | | | |
| FY 2018 Plans: Dengue Vaccine Block II: Will continue clinical development of the dengue human infection model, a tool used to evaluate and down select candidates transitioning from science and technology (S&T). Treatment for Resistant Wound Infections: Conduct safety and effectiveness clinical study. Next Generation Malaria Prophylaxis: Will continue the retinal (eye) safety study (3 year study) started in FY16. Will prepare the protocols for the required soldier specific studies needed for the FDA review. Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): Will continue field testing and evaluation of several diagnostic product candidates to include: dengue, chikungunya and bacterial diarrhea. | | | |
| FY 2019 Plans: Dengue Vaccine Block II: Will continue the clinical development of the dengue human infection model (DHIM), a tool for rapid evaluation of efficacy of dengue vaccines and therapeutics. Treatment for Resistant Wound Infections: Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant animal models. Proposed solutions could be stand-alone treatments or adjuncts to established medical practice. Candidate treatments could be small-molecule drugs, biologicals | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | Date: February 2018 | |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 |
| such as bacteriophages, or antibodies. Next Generation Malaria Prophylaxis: Will continue the retinal (eye) safety study (3 year study) started in FY17. Address any FDA post-marketing approval requirements. Rapid Diagnostic and Detection Devices (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. | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: Decrease in funding of \$19 dollars in FY19 was due to price adjustments. | | | |
| Accomplishments/Planned Programs Subtotals | | 14.382 | 14.372 |
| C. Other Program Funding Summary (\$ in Millions) N/A | | | |
| Remarks | | | |
| D. Acquisition Strategy Test and evaluate in-house and commercially developed products in extensive government-managed clinical trials to gather data required for FDA licensure and Environmental Protection Agency registration. | | | |
| E. Performance Metrics N/A | | | |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 808 / DoD Drug & Vacc Ad | | | | | |
| Management Services (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not Applicable : Not applicable | 19.535 | 2.030 | | 2.520 | | 2.511 | | - | | 2.511 | Continuing | Continuing | Continuing |
| Medical Product Development Management Services Cost | PO | General Dynamics Information Technology, : Frederick MD | 2.493 | 2.086 | | 2.454 | | 2.322 | | - | | 2.322 | 0.000 | 9.355 | - |
| Subtotal | | | 22.028 | 4.116 | | 4.974 | | 4.833 | | - | | 4.833 | Continuing | Continuing | N/A |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not applicable : Not applicable | 28.430 | 2.036 | | 2.803 | | - | | - | | - | Continuing | Continuing | Continuing |
| Rapid Diagnostic and Detection Devices | C/Various | Inbios, Inc : Seattle WA | - | - | | - | | 2.051 | | - | | 2.051 | 0.000 | 2.051 | - |
| Subtotal | | | 28.430 | 2.036 | | 2.803 | | 2.051 | | - | | 2.051 | Continuing | Continuing | N/A |
| Support (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not Applicable : Not applicable | 13.194 | 2.527 | | - | | 1.220 | | - | | 1.220 | Continuing | Continuing | Continuing |
| Subtotal | | | 13.194 | 2.527 | | - | | 1.220 | | - | | 1.220 | Continuing | Continuing | N/A |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 808 / DoD Drug & Vacc Ad | | | | | |
| Test and Evaluation (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not applicable : Not applicable | 51.149 | 2.703 | | 3.251 | | 0.548 | | - | | 0.548 | Continuing | Continuing | Continuing |
| Dengue Block II | IA | WRAIR and AFRIMS : Silver Spring MD | - | 0.800 | | 1.144 | | 3.302 | | - | | 3.302 | 0.000 | 5.246 | - |
| Malaria Prophylaxis clinical trial | TBD | TBD : TBD | 5.099 | 2.200 | | 2.200 | | 2.050 | | - | | 2.050 | 0.000 | 11.549 | - |
| Subtotal | | | 56.248 | 5.703 | | 6.595 | | 5.900 | | - | | 5.900 | Continuing | Continuing | N/A |
| | | | Prior Years | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract |
| Project Cost Totals | | | 119.900 | 14.382 | | 14.372 | | 14.004 | | - | | 14.004 | Continuing | Continuing | N/A |
| Remarks | | | | | | | | | | | | | | | |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2019 Army | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i> | |

| Event Name | FY 2017 | | | | FY 2018 | | | | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | |
|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 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 |
| Topical Antileishmanial Cream Expanded Access Treatment Pg | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Dengue Vaccine Block II Human Infection model studies | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Treatment for Resistant Wound Infections Phase 2 safety trial | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| D5P Next Generation Malaria Drug Clinical Studies | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Rapid Human Diagnostic Devices | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 808 / <i>DoD Drug & Vacc Ad</i> | |

Schedule Details

| Events | Start | | End | |
|---|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Topical Antileishmanial Cream Expanded Access Treatment Pgm | 2 | 2011 | 1 | 2017 |
| Dengue Vaccine Block II Human Infection model studies | 1 | 2016 | 4 | 2019 |
| Treatment for Resistant Wound Infections Phase 2 safety trial | 1 | 2016 | 4 | 2019 |
| D5P Next Generation Malaria Drug Clinical Studies | 1 | 2016 | 4 | 2017 |
| Rapid Human Diagnostic Devices | 4 | 2017 | 4 | 2022 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 811 / Mil HIV Vac&Drug Dev | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| 811: Mil HIV Vac&Drug Dev | - | 4.120 | 5.230 | 5.296 | - | 5.296 | 5.460 | 5.603 | 5.973 | 1.110 | 0.000 | 32.792 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |
| A. Mission Description and Budget Item Justification | | | | | | | | | | | | |
| This project funds development of militarily relevant human immunodeficiency virus (HIV) medical countermeasures. It provides for the planning and conduct of human clinical trials in a group of healthy volunteers to assess for safety and tolerability of medical countermeasures, how the drug/vaccine is distributed through, metabolized in, and excreted from the body, and to investigate the appropriate dose. Development efforts are focused on militarily unique needs affecting manning, mobilization, and deployment. The cumulative cost of treating HIV-positive DoD personnel is estimated to be \$16.6 billion for 3000 personnel over a 50-year lifetime. All clinical trials are conducted in accordance with U.S. FDA regulations. | | | | | | | | | | | | |
| Research efforts are coordinated with the National Institutes of Health and the National Institute of Allergy and Infectious Diseases (NIAID), Division of Acquired Immune Deficiency Syndrome (DAIDS). | | | | | | | | | | | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | | | | | | | | FY 2017 | FY 2018 | FY 2019 |
| Title: Military HIV Vaccine & Drug Development | | | | | | | | | | 4.120 | 5.230 | 5.296 |
| Description: This Project funds advanced development research to develop candidate HIV vaccines, assess their safety and effectiveness in evaluations with human subjects, and protect military personnel from risks associated with HIV infection. | | | | | | | | | | | | |
| FY 2018 Plans: Regional Vaccine Candidate: Completing execution of cohort study in high risk population in Thailand in preparation for start of clinical trial to Phase IIb/III effectiveness testing (testing to determine safety and performance) of vaccine regimen. | | | | | | | | | | | | |
| Global Vaccine Candidate: Developing human safety study test plan for new HIV vaccine components. Initiating regulatory and scientific reviews of human safety study test plan. Preparing clinical safety study sites in Africa to execute the study of the global vaccine. Global vaccine has moved up in priority because it meets the manufacturing capability requirement and can meet the Capability Development Document threshold in one step as opposed to incrementally. | | | | | | | | | | | | |
| FY 2019 Plans: New components of the regional vaccine will be tested in FY19. This testing will determine if improved effectiveness can be achieved. This study will be conducted in three regions, and is supported by the U.S. Army and DAIDS. The cohort studies in Thailand and Germany will be completed in FY19, with results available by the end of the FY. Selection of clinical sites for future effectiveness studies will be initiated. | | | | | | | | | | | | |
| FY 2018 to FY 2019 Increase/Decrease Statement: | | | | | | | | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | Date: February 2018 | |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) The minor increase of funding in FY 19 was due to inflation factor. | | FY 2017 | FY 2018 |
| | | FY 2019 | |
| Accomplishments/Planned Programs Subtotals | | 4.120 | 5.230 |
| | | 5.296 | |
| C. Other Program Funding Summary (\$ in Millions) N/A Remarks D. Acquisition Strategy Test and evaluate commercially developed drug/vaccine candidates in government-managed trials. E. Performance Metrics N/A | | | |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 811 / Mil HIV Vac&Drug Dev | | | | |

| Management Services (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | Not Applicable : Not Applicable | 3.161 | 0.119 | | 0.852 | | - | | - | | - | Continuing | Continuing | Continuing |
| Subtotal | | | 3.161 | 0.119 | | 0.852 | | - | | - | | - | Continuing | Continuing | N/A |

| | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Remarks Not Applicable | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | Not applicable : Not applicable | 3.797 | 0.284 | | 0.997 | | - | | - | | - | Continuing | Continuing | Continuing |
| Subtotal | | | 3.797 | 0.284 | | 0.997 | | - | | - | | - | Continuing | Continuing | N/A |

| Support (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | TBD : TBD | 2.282 | 0.157 | | 1.112 | | - | | - | | - | 0.000 | 3.551 | - |
| Subtotal | | | 2.282 | 0.157 | | 1.112 | | - | | - | | - | 0.000 | 3.551 | N/A |

| | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Remarks Not Applicable | | | | | | | | | | | | | | | |
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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 811 / Mil HIV Vac&Drug Dev | | | | | |

| Test and Evaluation (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | Not applicable : Not Applicable | 19.978 | 3.560 | | 2.269 | | 5.296 | | - | | 5.296 | 0.000 | 31.103 | - |
| Subtotal | | | 19.978 | 3.560 | | 2.269 | | 5.296 | | - | | 5.296 | 0.000 | 31.103 | N/A |

| | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| Remarks Not Applicable | | | | | | | | | | | | | | | |
|----------------------------------|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

| | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract |
|----------------------------|-------------|---------|---------|--------------|-------------|---------------|------------------|------------|--------------------------|
| Project Cost Totals | 29.218 | 4.120 | 5.230 | 5.296 | - | 5.296 | Continuing | Continuing | N/A |

| | | | | | | | | | |
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| Remarks | | | | | | | | | |
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| Exhibit R-4, RDT&E Schedule Profile: PB 2019 Army | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</i> | |

| Event Name | FY 2017 | | | | FY 2018 | | | | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | |
|--|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 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 |
| RV305A Amendment to add open-label boost to volunteers | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RV306 Intensive Immune Monitoring of Prime-Boost Vaccine | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RV328 Intensive Immune Monitoring of AIDSVAXB/E alone | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RV Candidate Cohort development for efficacy studies | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RV Candidate Immune Characterization for protective immunity | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 811 / <i>Mil HIV Vac&Drug Dev</i> | |

Schedule Details

| Events | Start | | End | |
|--|----------------|-------------|----------------|-------------|
| | Quarter | Year | Quarter | Year |
| RV305A Amendment to add open-label boost to volunteers | 3 | 2015 | 2 | 2017 |
| RV306 Intensive Immune Monitoring of Prime-Boost Vaccine | 2 | 2011 | 4 | 2017 |
| RV328 Intensive Immune Monitoring of AIDSVAXB/E alone | 4 | 2014 | 1 | 2018 |
| RV403 to evaluate adjuvant's ability to enhance durability | 2 | 2015 | 3 | 2015 |
| RV Candidate Cohort development for efficacy studies | 4 | 2016 | 4 | 2018 |
| RV Candidate Immune Characterization for protective immunity | 1 | 2019 | 2 | 2022 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 836 / Field Medical Systems Advanced Development | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| 836: Field Medical Systems Advanced Development | - | 17.334 | 13.604 | 14.691 | - | 14.691 | 17.599 | 18.022 | 19.937 | 16.871 | 0.000 | 118.058 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |
| A. Mission Description and Budget Item Justification | | | | | | | | | | | | |
| This Project funds the demonstration and validation of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. This Project funds human clinical trials to test the safety and effectiveness of biologics (products derived from living organisms) and devices necessary to meet medical requirements. When available, commercial-off-the-shelf (COTS) medical products are also tested and evaluated for transition to engineering and manufacturing development. Consideration is also given to reducing the medical logistics footprint through smaller weight, volume, and equipment independence from supporting materials. All clinical trials are conducted in accordance with U.S. FDA regulations. | | | | | | | | | | | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | | | | | | | | FY 2017 | FY 2018 | FY 2019 | |
| Title: Field Medical Systems Advanced Development - Program Management (PM) Medical Devices | | | | | | | | | 14.463 | 10.848 | 8.349 | |
| Description: Advanced Concept Development funding is provided for the following development of medical devices in support of enhanced combat casualty care. | | | | | | | | | | | | |
| FY 2018 Plans: Compartment Syndrome Pressure Device: This Project transitioned to Defense Health Program funding in FY17. | | | | | | | | | | | | |
| Junctional / Noncompressible Hemorrhage Control Agent: Developmental efforts will be completed and available for procurement. Intrathoracic Pressure Regulation Therapy (IPRT): Perform operational and suitability testing. Achieve Milestone B. Field Anesthesia: Performing a pivotal clinical trial on the device and working to finalize the design for production and obtain FDA clearance/approval. Ocular Drug Delivery (Ocular Salvage Device): Starting clinical trials. Complete Milestone A and finalize the capability development document. Portable Extracorporeal Membrane Oxidation (ECMO) device: Conduct clinical validation of prototype device. Work towards Milestone B accomplishment. Non-invasive neuro assessment device (NINAD): Product will transition to Advanced Development in FY18. Prepare for FDA submission and initiate clinical trials. | | | | | | | | | | | | |
| FY 2019 Plans: Field Anesthesia: Will continue clinical trials and prototype comparison. Temporary Corneal Repair (TCR): Continue down select activities. | | | | | | | | | | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 |
| Portable ECMO: Will continue clinical trials and device refinement. NINAD: Will continue FDA clinical trial for the indication for use of diagnosing mild traumatic brain injury. FY 2018 to FY 2019 Increase/Decrease Statement: Funding decrease was due to a shift in priorities from PM Devices to other PMs to fund higher priority efforts. | | | | |
| Title: Field Medical Systems Advanced Development - PM Medical Support Systems Description: Funding is provided for the following effort in the development of products that support the medical mission in combat casualty care and health care operations. FY 2018 Plans: Next Generation Uniform Repellent/Impregnation: Transitioning to PE 0604807A/Project 832. Litter Transport Shock/Stressor Mitigation System (Formally: NGIS): Transitioning to PE 0604807A/Project 832. Remote Triage Sensor System: Transitioning to PE 0604807A/Project 832. Nett Warrior Enhanced Physiological Sensors (Wearable): Collaborating with Program Executive Office (PEO) Soldier on the development of wearable physiological sensors. FY 2019 Plans: Nett Warrior Enhanced Wearable Sensors: Will continue to collaborate with Program Executive Office Soldier on the development of wearable sensors. Semi-autonomous casualty evacuation (CASEVAC) Ground Platform (S-MET): Will collaborate with PEO Combat Systems & Combat Support Systems on the Ground Mobility Vehicle Infantry Squad Variant (GMVISV). FY 2018 to FY 2019 Increase/Decrease Statement: The increase of funding in FY19 is due to the planned progression of medical products under development, in collaboration with other PEOs. | | 2.871 | 2.494 | 2.656 |
| Title: Field Medical Systems Advanced Development - PM Tissue Injury and Regenerative Medicine Description: Funding for engineering and manufacturing development of tissue injury and regenerative medicine health products for enhanced medical capability and readiness FY 2018 Plans: Fracture Putty: Transition ?Fracture Putty? scaffold product from Science & Technology. Supporting Fracture Putty?s scale-up development, validation, and required FDA regulatory activities to achieve a commercial product. FY 2019 Plans: | | - | 0.262 | 2.365 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | Date: February 2018 | |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i> | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 |
| <p>Topical Burn Conversion Prevention Product: Will submit an Investigational Device Exemption, and will prepare for safety and effectiveness trials for a product to prevent superficial burn wounds from developing into deep partial and full thickness burn injuries.</p> <p>Systemic Burn Conversion Prevention Product: Will initiate manufacturing of material and Phase 2 clinical trial (safety and effectiveness) for a product used as an intravenous treatment in burn injuries.</p> <p>Permanent Acellular Arterial Graft: Will initiate manufacturing of material and a Phase 2 (safety and efficacy) clinical trial to support vascular grafting for extremity repair and reconstruction.</p> <p><i>FY 2018 to FY 2019 Increase/Decrease Statement:</i> The increase of funding in FY19 is due to the planned progression of two burn medical products in development.</p> | | | |
| <p><i>Title:</i> Field Medical Systems Advanced Development - PM Pharmaceutical Systems</p> <p><i>Description:</i> Funding is provided for engineering and manufacturing development of medical products managed by Program Manager (PM) Pharmaceuticals for enhanced combat casualty care and follow-on care, including rehabilitation.</p> <p><i>FY 2019 Plans:</i> Cold Stored Platelets in Platelet Additive Solution: Will complete studies for product characterization and labeling information and effectiveness.</p> <p><i>FY 2018 to FY 2019 Increase/Decrease Statement:</i> Increase is due to blood related product studies scheduled in FY19.</p> | | - | - |
| | | | 1.321 |
| Accomplishments/Planned Programs Subtotals | | 17.334 | 13.604 |
| C. Other Program Funding Summary (\$ in Millions) | | | |
| N/A | | | |
| Remarks | | | |
| D. Acquisition Strategy | | | |
| Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding. | | | |
| E. Performance Metrics | | | |
| N/A | | | |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
|--|------------------------|--|-------------|---------|------------|---|------------|--------------|------------|---|------------|---------------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 836 / Field Medical Systems Advanced Development | | | | | |
| Management Services (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not Applicable : Not applicable | 41.811 | 3.124 | | 1.009 | | 0.974 | | - | | 0.974 | Continuing | Continuing | Continuing |
| Medical Product Development Management Services Cost | C/IDIQ | Not applicable : Not applicable | - | 1.200 | | - | | 1.185 | | - | | 1.185 | 0.000 | 2.385 | - |
| Subtotal | | | 41.811 | 4.324 | | 1.009 | | 2.159 | | - | | 2.159 | Continuing | Continuing | N/A |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 |
| Product Development | TBD | TBD : TBD | 0.932 | - | | - | | - | | - | | - | 0.000 | 0.932 | - |
| Medical Product Development | TBD | ALL Product : Various | 1.931 | 1.083 | | 0.850 | | 2.368 | | - | | 2.368 | Continuing | Continuing | Continuing |
| Product Development of Freeze-dried plasma | TBD | TBD : TBD | 8.778 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Point of Care Coagulation Profiler | TBD | TBD : TBD | 0.385 | - | | - | | - | | - | | - | 0.000 | 0.385 | - |
| TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits) | TBD | Banyan BioMarkers, Inc : Alachua FL | 13.231 | 2.583 | | - | | - | | - | | - | 0.000 | 15.814 | - |
| Impedance Threshold Device for the Treatment of Traumatic Brain Injury | TBD | Advance Circulatory Systems Inc. : Roseville, MN | 2.322 | - | | 0.626 | | - | | - | | - | 0.000 | 2.948 | - |
| Compartment Syndrome Pressure Device | TBD | Twinstar : Minniapolis, MN | 1.871 | - | | - | | - | | - | | - | 0.000 | 1.871 | - |
| Hydration Status Monitor | TBD | Gaia Medical : LaJolla CA | 0.841 | - | | - | | - | | - | | - | 0.000 | 0.841 | - |
| Noninvasive Neuromodulator TBI | TBD | TBD : TBD | 2.036 | - | | 2.298 | | - | | - | | - | 0.000 | 4.334 | - |
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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 836 / Field Medical Systems Advanced Development | | | | | |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 |
| PTSD | Various | TBD : Various locations | - | 2.032 | | 2.300 | | - | | - | | - | 0.000 | 4.332 | - |
| Ocular Salvage Device | Various | TBD : TBD | - | 2.479 | | 2.461 | | - | | - | | - | 0.000 | 4.940 | - |
| Field Anesthesia | TBD | TBD : Various | - | 2.568 | | 3.262 | | 1.120 | | - | | 1.120 | 0.000 | 6.950 | - |
| Field Sterilizer | TBD | TBD : TBD | 3.515 | - | | - | | 3.221 | | - | | 3.221 | 0.000 | 6.736 | - |
| Product Development | TBD | HemCon Medical Technologies : Tigard, Oregon | 9.720 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Product Development | TBD | Banyan BioMarkers, Inc : Alachua FL | 31.514 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Development of Platelet Derived Hemostatic agent | TBD | Fast Track Drugs & Biologics : Frederick, MD | 1.800 | - | | - | | - | | - | | - | Continuing | Continuing | Continuing |
| Non-invasive neuro assessment device (NINAD) | C/Various | TBD : TBD | - | 0.800 | | - | | 3.074 | | - | | 3.074 | 0.000 | 3.874 | - |
| Advanced Refrigerated Platelet Storage Technology | C/Various | TBD : TBD | - | - | | - | | 0.985 | | - | | 0.985 | 0.000 | 0.985 | - |
| Subtotal | | | 78.876 | 11.545 | | 11.797 | | 10.768 | | - | | 10.768 | Continuing | Continuing | N/A |
| Support (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | Not Applicable : Not applicable | 45.720 | 0.744 | | 0.548 | | 1.152 | | - | | 1.152 | Continuing | Continuing | Continuing |
| Subtotal | | | 45.720 | 0.744 | | 0.548 | | 1.152 | | - | | 1.152 | Continuing | Continuing | N/A |
| Remarks | | | | | | | | | | | | | | | |
| No product/contract costs greater than \$1M individually. | | | | | | | | | | | | | | | |
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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) 836 / Field Medical Systems Advanced Development | | | | | |
| Test and Evaluation (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | Not applicable : Not applicable | 37.693 | 0.721 | | 0.250 | | 0.612 | | - | | 0.612 | Continuing | Continuing | Continuing |
| Subtotal | | | 37.693 | 0.721 | | 0.250 | | 0.612 | | - | | 0.612 | Continuing | Continuing | N/A |
| Remarks No product/contract costs greater than \$1M individually. | | | | | | | | | | | | | | | |
| | | | Prior Years | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract |
| Project Cost Totals | | | 204.100 | 17.334 | | 13.604 | | 14.691 | | - | | 14.691 | Continuing | Continuing | N/A |
| Remarks | | | | | | | | | | | | | | | |

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| Exhibit R-4, RDT&E Schedule Profile: PB 2019 Army | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i> | |

| Event Name | FY 2017 | | | | FY 2018 | | | | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | |
|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
| | 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 |
| Temporary Corneal Repair | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Noninvasive Neuro Assessment Device development | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Intrathoracic Pressure Regulation Therapy | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Field Anesthesia | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Cold Stored Platelets in Platelet Additive solution | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) 836 / <i>Field Medical Systems Advanced Development</i> | |

Schedule Details

| Events | Start | | End | |
|---|----------------|-------------|----------------|-------------|
| | Quarter | Year | Quarter | Year |
| Temporary Corneal Repair | 2 | 2016 | 1 | 2021 |
| Noninvasive Neuro Assessment Device development | 1 | 2016 | 1 | 2023 |
| Intrathoracic Pressure Regulation Therapy | 4 | 2015 | 1 | 2023 |
| Field Anesthesia | 4 | 2017 | 3 | 2022 |
| Cold Stored Platelets in Platelet Additive solution | 4 | 2017 | 4 | 2023 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | | | Project (Number/Name) CS4 / <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| CS4: <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i> | - | 7.500 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 7.500 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification
 Congressional Interest Item funding for medical systems advanced development initiatives in Transport Telemedicine - Initiate Joint Advanced Technology Demonstration for MEDHUB to provide Medical Treatment Facility (MTF) automatic situational awareness system to identify patients en-route to MTFs and automate paramedic tasks.

| | | |
|--|----------------|----------------|
| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2017 | FY 2018 |
| Congressional Add: Congressional Special Interest_ Transport Telemedicine | 7.500 | - |
| FY 2017 Accomplishments: N/A | | |
| Congressional Adds Subtotals | 7.500 | - |

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

Remarks

D. Acquisition Strategy
 N/A

E. Performance Metrics
 N/A

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) CS4 / MEDICAL SYSTEMS ADV DEV INITIATIVES (CA) | | | | | |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 |
| Telemedicine product development | C/TBD | TBD / : TBD | - | 7.500 | | - | | - | | - | | - | 0.000 | 7.500 | - |
| Subtotal | | | - | 7.500 | | - | | - | | - | | - | 0.000 | 7.500 | N/A |
| | | | Prior Years | FY 2017 | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract | |
| Project Cost Totals | | | - | 7.500 | 0.000 | | - | | - | | - | 0.000 | 7.500 | N/A | |
| Remarks | | | | | | | | | | | | | | | |

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PE 0603807A: Medical Systems Advanced Development
Army

R-1 Line #68

[illegible]

PE 0603807A / Medical Systems Advanced Development

CS4 / MEDICAL SYSTEMS ADV DEV
INITIATIVES (CA)[illegible]

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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) CS4 / <i>MEDICAL SYSTEMS ADV DEV INITIATIVES (CA)</i> | |

Schedule Details

| Events | Start | | End | |
|--|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Telemedicine product development (MEDHUB) - Develop MEDHUB Prototype | 2 | 2018 | 1 | 2019 |
| Telemedicine product development (MEDHUB) - Peripheral Integration | 1 | 2018 | 1 | 2019 |
| Telemedicine product development (MEDHUB) - Software Development | 1 | 2018 | 1 | 2019 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | | | Project (Number/Name) FF4 / <i>Counterdrug, DDR, Sys Development & Demonstration</i> | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| FF4: <i>Counterdrug, DDR, Sys Development & Demonstration</i> | - | 4.000 | 0.000 | 0.000 | - | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 0.000 | 4.000 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

A. Mission Description and Budget Item Justification
 Supports the Secretary of Defense approved counterdrug advanced development efforts used in a major re-design of the Forensic Toxicology Drug Testing Laboratory (FTDTL) information management system used to test urine samples for the presence of illegal drugs. The Drug Testing Program - Client Collection System (DTP-CSS) is comprised of several variations of a desktop application used to select service members for random drug testing, prepare labels for urine specimen bottles, and print corresponding chain-of-custody documents. This Project will standardize DTP-CSS across all services and migrate it to a Web-based system.

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| B. Accomplishments/Planned Programs (\$ in Millions) | FY 2017 | FY 2018 | FY 2019 |
| Title: Development and demonstration of tracking laboratory urine samples used in drug testing | 4.000 | - | - |
| Accomplishments/Planned Programs Subtotals | 4.000 | - | - |

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

Remarks

D. Acquisition Strategy
 N/A

E. Performance Metrics
 N/A

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) FF4 / Counterdrug, DDR, Sys Development & Demonstration | | | | | |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 |
| Product Development | C/UCA | Alliant Corps LLC : San Antonio, TX | 4.400 | 4.000 | | - | | - | | - | | - | 0.000 | 8.400 | - |
| Subtotal | | | 4.400 | 4.000 | | - | | - | | - | | - | 0.000 | 8.400 | N/A |
| | | | Prior Years | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract |
| Project Cost Totals | | | 4.400 | 4.000 | | 0.000 | | - | | - | | - | 0.000 | 8.400 | N/A |
| Remarks | | | | | | | | | | | | | | | |

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PE 0603807A: Medical Systems Advanced Development
Army

Date: February 2018

Appropriation/Budget Activity
2040 / 4

R-1 Program Element (Number/Name)
PE 0603807A / Medical Systems Advanced Development

Project (Number/Name)
FF4 / Counterdrug, DDR, Sys Development
& Demonstration

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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) FF4 / <i>Counterdrug, DDR, Sys Development & Demonstration</i> | |

Schedule Details

| Events | Start | | End | |
|--------------------------------|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Determine Hosting requirements | 2 | 2017 | 2 | 2017 |
| Coding and Development Testing | 3 | 2017 | 1 | 2019 |
| User Testing | 1 | 2019 | 2 | 2019 |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | | | | | | | | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev | | | |
| COST (\$ in Millions) | Prior Years | FY 2017 | FY 2018 | FY 2019 Base | FY 2019 OCO | FY 2019 Total | FY 2020 | FY 2021 | FY 2022 | FY 2023 | Cost To Complete | Total Cost |
| VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev | - | 0.000 | 0.285 | 0.293 | - | 0.293 | 0.293 | 0.302 | 0.311 | 0.000 | 0.000 | 1.484 |
| Quantity of RDT&E Articles | - | - | - | - | - | - | - | - | - | - | | |

Note

Medical Evacuation Enroute Care Validation Study is completed in Fiscal Year (FY) 2015. Products from this project transition to Program element (PE) 0604807A/ Project VS8 in FY 16.

A. Mission Description and Budget Item Justification

Original models of Army Black Hawk Medical Evacuation (MEDEVAC) helicopters continue to play a major role in maintaining high U.S. troop survival rates in Iraq and Afghanistan by evacuating wounded troops in less than one-hour. In 2009 a Vice Chief of Staff, Army (VCSA)-approved force design update increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs. In 2010, the U.S. Army Medical Department (AMEDD) accepted life-cycle management of the MEDEVAC Evacuation Package (MEP) from PEO Aviation. In order to achieve required operational capability and enhance commonality across the MEDEVAC fleet, the MEDEVAC MEP program upgrades, retrofits, trains, and sustains the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.

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

| | FY 2017 | FY 2018 | FY 2019 |
|--|----------------|----------------|----------------|
| Title: Medical Evacuation Development | - | 0.285 | 0.293 |
| Description: This activity performs Aeromedical Evacuation Cabin and Technology Research to determine the optimum space and configuration for performing necessary life-saving paramedic-level tasks. Efforts will develop patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers' lives during point of injury MEDEVAC Missions. | | | |
| FY 2018 Plans: Medical Evacuation Development: Aeromedical Evacuation Cabin and Technology Research is determining optimum space and configuration in order to perform necessary life-saving paramedic-level tasks. Developing patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers' lives during point of injury MEDEVAC Missions. | | | |
| FY 2019 Plans: Future Vertical Lift (FVL) Aeromedical Evacuation Cabin Space and Technology Research and Design (Medical Evacuation Development): Determine optimum space and configuration to perform life-saving paramedic-level tasks in current and future | | | |

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| Exhibit R-2A, RDT&E Project Justification: PB 2019 Army | | Date: February 2018 | | |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> | | |
| B. Accomplishments/Planned Programs (\$ in Millions) | | FY 2017 | FY 2018 | FY 2019 |
| evacuation platforms. Will develop patient handling system components and prototypes to ensure paramedic skills and tasks are performed to standard to save Soldiers' lives during MEDEVAC Missions. | | | | |
| <i>FY 2018 to FY 2019 Increase/Decrease Statement:</i> Increase in funding in FY19 is due to inflation factors. | | | | |
| Accomplishments/Planned Programs Subtotals | | - | 0.285 | 0.293 |
| C. Other Program Funding Summary (\$ in Millions) N/A | | | | |
| Remarks | | | | |
| D. Acquisition Strategy Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC and regulatory requirements for production and fielding. | | | | |
| E. Performance Metrics N/A | | | | |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | | | Date: February 2018 | | | |
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| Appropriation/Budget Activity 2040 / 4 | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev | | | | | |
| Management Services (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | APM MEDEVAC : Huntsville, AL | 0.189 | - | | 0.129 | | 0.293 | | - | | 0.293 | 0.000 | 0.611 | - |
| Subtotal | | | 0.189 | - | | 0.129 | | 0.293 | | - | | 0.293 | 0.000 | 0.611 | N/A |
| Product Development (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | APM MEDEVAC PEO Aviation : Huntsville AL | 1.479 | - | | 0.156 | | - | | - | | - | 0.000 | 1.635 | - |
| Subtotal | | | 1.479 | - | | 0.156 | | - | | - | | - | 0.000 | 1.635 | N/A |
| Support (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | TBD | APM MEDEVAC : Huntsville, AL | 0.911 | - | | - | | - | | - | | - | 0.000 | 0.911 | - |
| Subtotal | | | 0.911 | - | | - | | - | | - | | - | 0.000 | 0.911 | N/A |
| Test and Evaluation (\$ in Millions) | | | | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 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 | MIPR | APM MEDEVAC PEO Aviation : Huntsville, AL | 0.199 | - | | - | | - | | - | | - | 0.000 | 0.199 | - |
| Subtotal | | | 0.199 | - | | - | | - | | - | | - | 0.000 | 0.199 | N/A |

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2019 Army | | | | | | | | | | Date: February 2018 | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | R-1 Program Element (Number/Name) PE 0603807A / <i>Medical Systems Advanced Development</i> | | | | | Project (Number/Name) VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> | | | |
| | Prior Years | FY 2017 | | FY 2018 | | FY 2019 Base | | FY 2019 OCO | | FY 2019 Total | Cost To Complete | Total Cost | Target Value of Contract |
| Project Cost Totals | 2.778 | - | | 0.285 | | 0.293 | | - | | 0.293 | 0.000 | 3.356 | N/A |
| Remarks | | | | | | | | | | | | | |
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| Exhibit R-4, RDT&E Schedule Profile: PB 2019 Army | | | | | | | | | | | | | | | | Date: February 2018 | | | | | | | | | | | | | | | | |
| Appropriation/Budget Activity 2040 / 4 | | | | | | | | | | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | | | | | | | | Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev | | | | | | | | | | | | | | |
| Event Name | FY 2017 | | | | FY 2018 | | | | FY 2019 | | | | FY 2020 | | | | FY 2021 | | | | FY 2022 | | | | FY 2023 | | | | | | | |
| | 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 | | | | |
| Telemedicine Research and Development and Data Transfer | [REDACTED] | | | | | | | | [REDACTED] | | | | | | | | [REDACTED] | | | | [REDACTED] | | | | [REDACTED] | | | | [REDACTED] | | | |
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| Exhibit R-4A, RDT&E Schedule Details: PB 2019 Army | | | Date: February 2018 |
| Appropriation/Budget Activity 2040 / 4 | R-1 Program Element (Number/Name) PE 0603807A / Medical Systems Advanced Development | Project (Number/Name) VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev | |

Schedule Details

| Events | Start | | End | |
|---|---------|------|---------|------|
| | Quarter | Year | Quarter | Year |
| Telemedicine Research and Development and Data Transfer | 1 | 2016 | 4 | 2019 |