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| <b>Exhibit R-2, RDT&amp;E Budget Item Justification: FY 2018 Army</b> | <b>Date: May 2017</b> |
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| <b>Appropriation/Budget Activity</b><br>2040: Research, Development, Test & Evaluation, Army / BA 5: System Development & Demonstration (SDD) |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |                      |                |                |                |                |                         |                   |
|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| <b>COST (\$ in Millions)</b>  | <b>Prior Years</b> | <b>FY 2016</b> | <b>FY 2017</b> | <b>FY 2018 Base</b> | <b>FY 2018 OCO</b>  | <b>FY 2018 Total</b> | <b>FY 2019</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> | <b>Cost To Complete</b> | <b>Total Cost</b> |
| Total Program Element   | -                  | 39.295         | 41.124         | 39.238              | -   | 39.238               | 45.503         | 50.124         | 51.490         | 51.213         | Continuing              | Continuing        |
| 812: Mil HIV Vac&Drug Dev   | -                  | 0.332          | 4.557          | 1.183               | -   | 1.183                | 1.192          | 1.215          | 1.244          | 1.080          | Continuing              | Continuing        |
| 832: Field Medical Systems Engineering Development  | -                  | 23.119         | 23.532         | 24.812              | -   | 24.812               | 29.438         | 32.443         | 33.347         | 32.743         | Continuing              | Continuing        |
| 849: Infec Dis Drug/Vacc Ed   | -                  | 15.461         | 12.922         | 13.243              | -   | 13.243               | 14.873         | 16.466         | 16.899         | 17.390         | Continuing              | Continuing        |
| VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev  | -                  | 0.383          | 0.113          | 0.000               | -   | 0.000                | 0.000          | 0.000          | 0.000          | 0.000          | Continuing              | Continuing        |

**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).

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.

Project VS8 program receives products that transition from VS7 and funds effort to complete research and development for the medical evacuation (MEDEVAC) Mission Essential Packages (MEPs) to support 256 Medical Evacuation legacy helicopters. The Army's force design increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs.

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

| <b>B. Program Change Summary (\$ in Millions)</b> | <b><u>FY 2016</u></b> | <b><u>FY 2017</u></b> | <b><u>FY 2018 Base</u></b> | <b><u>FY 2018 OCO</u></b> | <b><u>FY 2018 Total</u></b> |
|---|-----------------------|-----------------------|----------------------------|---------------------------|-----------------------------|
| Previous President's Budget                       | 45.412                | 41.124                | 43.603                     | -                         | 43.603                      |
| Current President's Budget                        | 39.295                | 41.124                | 39.238                     | -                         | 39.238                      |
| Total Adjustments                                 | -6.117                | 0.000                 | -4.365                     | -                         | -4.365                      |
| • Congressional General Reductions                | -                     | -                     |                            |                           |                             |
| • Congressional Directed Reductions               | -                     | -                     |                            |                           |                             |
| • Congressional Rescissions                       | -                     | -                     |                            |                           |                             |
| • Congressional Adds                              | -                     | -                     |                            |                           |                             |
| • Congressional Directed Transfers                | -                     | -                     |                            |                           |                             |
| • Reprogrammings                                  | -                     | -                     |                            |                           |                             |
| • SBIR/STTR Transfer                              | -1.616                | -                     |                            |                           |                             |
| • Adjustments to Budget Years                     | -4.501                | 0.000                 | -4.402                     | -                         | -4.402                      |
| • Civ Pay Adjustments                             | 0.000                 | 0.000                 | 0.037                      | -                         | 0.037                       |

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| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army  |             |         |         |              |   |               |         |         |   | Date: May 2017 |                  |            |
| Appropriation/Budget Activity<br>2040 / 5  |             |         |         |              | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |               |         |         | Project (Number/Name)<br>812 / Mil HIV Vac&Drug Dev |                |                  |            |
| COST (\$ in Millions)  | Prior Years | FY 2016 | FY 2017 | FY 2018 Base | FY 2018 OCO   | FY 2018 Total | FY 2019 | FY 2020 | FY 2021   | FY 2022        | Cost To Complete | Total Cost |
| 812: Mil HIV Vac&Drug Dev  | -           | 0.332   | 4.557   | 1.183        | -   | 1.183         | 1.192   | 1.215   | 1.244   | 1.080          | Continuing       | Continuing |
| Quantity of RDT&E Articles   | -           | -       | -       | -            | -   | -             | -       | -       | -   | -              |                  |            |
| <b>A. Mission Description and Budget Item Justification</b><br><p>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.</p> <p>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.</p>  |             |         |         |              |   |               |         |         |   |                |                  |            |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  |             |         |         |              |   |               |         |         | FY 2016   | FY 2017        | FY 2018          |            |
| <b>Title:</b> Military HIV Vaccine and Drug Development<br><b>Description:</b> 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.<br><b>FY 2016 Accomplishments:</b><br>Begin early testing of new Envelope glycoprotein 120 bivalent products in prime-boost format will allow for efficacy site preparation and potential trial start in first quarter (Q1) of Fiscal Year (FY) 17. Begin final site selection and ramp up of efficacy trial activities.<br><b>FY 2017 Plans:</b><br>Will conduct a Phase IIB efficacy study (trial to evaluate efficacy in patients with the disease) for the global HIV vaccine candidate.<br><b>FY 2018 Plans:</b><br>Will continue support of Regional vaccine Phase III (large safety and efficacy trial) in sub-Saharan Africa. Will support Global vaccine efficacy studies at multiple international Army-funded study sites. Support entails the performance of later stage Phase II (safety and effectiveness) and Phase III (pivotal effectiveness) clinical trials of selected Global HIV vaccine. |             |         |         |              |   |               |         |         | 0.332   | 4.557          | 1.183            |            |
| <b>Accomplishments/Planned Programs Subtotals</b>  |             |         |         |              |   |               |         |         | 0.332   | 4.557          | 1.183            |            |
| <b>C. Other Program Funding Summary (\$ in Millions)</b><br>N/A  |             |         |         |              |   |               |         |         |   |                |                  |            |

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| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army                                   |   | Date: May 2017                                      |
| Appropriation/Budget Activity<br>2040 / 5   | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev | Project (Number/Name)<br>812 / Mil HIV Vac&Drug Dev |
| C. Other Program Funding Summary (\$ in Millions)   |   |   |
| <u>Remarks</u>  |   |   |
| D. Acquisition Strategy   |   |   |
| Test and evaluate commercially developed vaccine candidates in government-managed trials. |   |   |
| E. Performance Metrics  |   |   |
| N/A   |   |   |

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| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army |                |         |         |                 |   |                  |         |         |   | Date: May 2017 |                     |               |
|---|----------------|---------|---------|-----------------|---|------------------|---------|---------|---|----------------|---------------------|---------------|
| Appropriation/Budget Activity<br>2040 / 5               |                |         |         |                 | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |                  |         |         | Project (Number/Name)<br>832 / Field Medical Systems Engineering<br>Development |                |                     |               |
| COST (\$ in Millions)                                   | Prior<br>Years | FY 2016 | FY 2017 | FY 2018<br>Base | FY 2018<br>OCO  | FY 2018<br>Total | FY 2019 | FY 2020 | FY 2021   | FY 2022        | Cost To<br>Complete | Total<br>Cost |
| 832: Field Medical Systems<br>Engineering Development   | -              | 23.119  | 23.532  | 24.812          | -   | 24.812           | 29.438  | 32.443  | 33.347  | 32.743         | Continuing          | Continuing    |
| 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. This Project 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. Mature commercial-off-the-shelf (COTS) medical products are also evaluated for military use. 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 United States (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 Diagnostics, Inc.; HemCon Medical Technologies; Cerdak Ltd; Hemerus Medical, LLC; Fast Track Drugs & Biologics, LLC; Integrated Medical Systems, Inc.; 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.

Others collaborating in this Project include Program Executive Office (PEO) Soldier, PEO Combat Service Support (CSS), and Naval Undersea Warfare Center.

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

|  | <b>FY 2016</b> | <b>FY 2017</b> | <b>FY 2018</b> |
|--|----------------|----------------|----------------|
| <b>Title:</b> Field Medical Systems Engineering Development PM Medical Devices   | 3.060          | 3.126          | 2.519          |
| <b>Description:</b> This effort funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by Program Manager (PM)-Medical Devices.   |                |                |                |
| <b>FY 2016 Accomplishments:</b><br>Oxygen Generator (15 LPM) System: In Fiscal Year (FY) 16, transition out of Advanced Development and is to be procured with Army procurement (OPA) funds. Replacement for the M-138 Steam Sterilizer: FDA clearance and Milestone C achieved. Request for Proposals projected early FY16. Medical Equipment Sets Development: Continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment is selected for modernization based on its own life cycle plan as part of Sets, Kits and Outfits (SKO). Modernization also occurs if a product will be discontinued, new models will be available and new technology will be developed to meet the users need. Traumatic Brain Injury (TBI) Diagnostic Assay System Increment II Point of Care Device: This product is transitioning from Army to Defense Health Program Research, Development, Test & |                |                |                |

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> FY 2018 Army   |   | <b>Date:</b> May 2017   |                |
| <b>Appropriation/Budget Activity</b><br>2040 / 5   | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev | <b>Project (Number/Name)</b><br>832 / Field Medical Systems Engineering Development |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  |   | <b>FY 2016</b>  | <b>FY 2017</b> |
| <p>Evaluation (RDTE) for further development. Noninvasive Neurodiagnostics TBI: The three technologies currently involve the Eye-Tracking System, the QEEG and Balance Platforms. None of these systems are anticipated to be ready at this time for transition to advanced development. Advanced Wound Dressing: Continuing to conduct comparative studies for the Advanced Wound Care commercial products (in-vivo animal or human studies).</p> <p><b>FY 2017 Plans:</b><br/>Oxygen Generator (15 LPM) System: will undergo airworthiness testing and will be procured with Army procurement (OPA) funds. Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Medical Equipment Sets Development: 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 SKO. Modernization also occurs if a product will be discontinued, new models will be available and new improved technology will be developed to meet the user's need. Junctional / Noncompressible Hemorrhage Control Agent: Will complete studies to achieve a broader indication, improve device feasibility, increase shelf life, decrease unit price, and improve manufacturing efficiency..</p> <p><b>FY 2018 Plans:</b><br/>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 SKO. Junctional / Noncompressible Hemorrhage Control Agent: Developmental efforts will be completed; available for procurement.</p> |   |   |                |
| <p><b>Title:</b> Field Medical Systems Engineering Development PM Pharmaceuticals</p> <p><b>Description:</b> Funding is provided for engineering and manufacturing development of medical products managed by PM Pharmaceuticals for enhanced combat casualty care and follow-on care, including rehabilitation.</p> <p><b>FY 2016 Accomplishments:</b><br/>Cryopreserved Platelets: Continue the Phase 2 Efficacy study in patients with complex cardiac bypass and/or thrombocytopenic patients with World Health Organization Grade 2 or higher bleeding. Continue development of Phase 3 (expanded safety, efficacy and dosing) clinical testing and protocols for pivotal study. Freeze-Dried Plasma Program: Continue the Phase 2 (safety and initial efficacy) clinical trials. Continue manufacturing development and validation of Freeze-Dried Plasma batches.</p> <p><b>FY 2017 Plans:</b><br/>Cryopreserved Platelets: Will continue the Phase 2 safety and efficacy study in patients with complex cardiac bypass and/or thrombocytopenic patients with World Health Organization Grade 2 or higher bleeding. Will continue development of Phase 3 (expanded safety, efficacy and dosing) clinical testing and protocols for pivotal study. Will begin the manufacturing development and validation of Cryopreserved platelet batches. Freeze-Dried Plasma Program: Will continue the Phase 2 (safety and</p>   |   | 13.978  | 14.951         |

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| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army   |   | Date: May 2017  |         |         |
| Appropriation/Budget Activity<br>2040 / 5   | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev | Project (Number/Name)<br>832 / Field Medical Systems Engineering<br>Development |         |         |
| B. Accomplishments/Planned Programs (\$ in Millions)  |   | FY 2016   | FY 2017 | FY 2018 |
| efficacy) clinical trials and prepare for Phase 3 clinical trial (confirming safety and efficacy in diverse populations). Will continue manufacturing development and validation of Freeze-Dried Plasma batches.  |   |   |         |         |
| FY 2018 Plans:<br>Cryopreserved Platelets: Will complete the in-life portion of the Phase 2 safety and effectiveness study in patients with complex cardiac bypass and/or who have an abnormally low amount of platelets. Will continue development of clinical testing protocols for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study. Will continue the manufacturing development and validation of Cryopreserved platelet batches. Freeze-Dried Plasma Program: Based on additional guidance from the FDA, a new Phase 1 dose escalation study that began in FY17 will continue in FY18. Will continue the preparation for a Phase 2 prospective clinical study (safety and efficacy study that follows patients over time to measure progress/outcomes).  |   |   |         |         |
| Title: Field Medical Systems Engineering Development PM Integrated Clinical Systems (ICS)<br>Description: This effort funds the engineering and manufacturing development of medical products managed by PM-Integrated Clinical Systems (PM-ICS) for enhanced combat casualty care and follow-on care, including rehabilitation.  |   | 4.213   | -       | -       |
| FY 2016 Accomplishments:<br>Pre-Hospital Medical Informatics Transport: Combat Developers begin the engineering and manufacturing development phase for the Pre-Hospital Medical Informatics Transport.   |   |   |         |         |
| Title: Field Medical Systems Engineering Development PM Medical Support Systems<br>Description: This effort funds the engineering and manufacturing development of medical products managed by PM Medical Support Systems for enhanced combat casualty care and follow-on care, including rehabilitation.   |   | 1.868   | 6.823   | 3.456   |
| FY 2016 Accomplishments:<br>Modernization of medical equipment sets: As part of the medical equipment sets, complete evaluations of commercial litters, cold chain storage devices and commercial items. Airworthiness Testing: Continue to evaluate modernization efforts and conduct airworthiness testing for medical equipment sets Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation. Per Army Regulation 70-62, Airworthiness Qualification of Aircraft Systems, all "carry-on" equipment, to include medical devices, must have an Airworthiness release. Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package (MEP): Continue collaboration with Program Executive Office (PEO) Combat Support/Combat Service Support (PEO CS&CSS) and PEO Ground Combat Systems (PEO GCS) on development efforts for AMPV evacuation and treatment platforms. Environmental Sentinel Biomonitor (ESB): Finish Advanced Development of Environmental Sentinel Biomonitor with a MS C planned for early FY16 and transition product to procurement. Waste Treatment System for the Combat Support Hospital: Transition from Small Business Innovation Research in FY16 due to delays in development/ prototype evaluation. Start development of Waste Treatment System |   |   |         |         |

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> FY 2018 Army   |  |  | <b>Date:</b> May 2017 |  |                |
| <b>Appropriation/Budget Activity</b><br>2040 / 5   |  | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> |                       | <b>Project (Number/Name)</b><br>832 / <i>Field Medical Systems Engineering Development</i> |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  |  |  | <b>FY 2016</b>        | <b>FY 2017</b>   | <b>FY 2018</b> |
| <p>(WTS) for the Combat Support Hospital. Altitude Readiness Management System (ARMS): Transition the ARMS product to PEO Soldier and closeout the Advance Development effort. Improved Vector Trap: Continue prototype development of Vector Traps for user evaluation. Portable Vector Identification Workstation: Complete user evaluation of the field deployable vector identification workstation and add to Entomology Set.</p> <p><b>FY 2017 Plans:</b><br/>           Modernization of medical equipment sets (MES): As part of the MES modernization, will evaluate the Combat Support Hospital water distribution system, environmental sampling devices, rodent collection/evaluation products, blood component freezers and commercial items. Airworthiness Testing: Will continue to conduct airworthiness testing for MES and MEP with products covering air and ground medical evacuation. Per Army Regulation 70-62, Airworthiness Qualification of Aircraft Systems, all "carry-on" equipment, to include medical devices, must have an Airworthiness release. Medical Evac and Treatment Vehicles MES, MEP, and casualty evacuation (CASEVAC): Will transition from Program Element (PE) 0603807 (Medical Systems Advanced Development) / Project 836 (Field Medical Systems Advanced Development). Will finalize the MES and MEP in collaboration with Program Executive Office Ground Combat Systems (PEO GCS) on development efforts for the Armored Multi-Purpose Vehicle Evacuation and Treatment platforms. Will work with PEO Combat Support/Service Support (CS &amp; CSS) for development and testing of the CASEVAC system for the Joint Light Tactical Vehicle (JLTV). Waste Treatment System (WTS) for the CSH: Product will transition from Rapid Innovation Fund for developmental testing and user evaluation. Improved Flying Vector Trap (IFVT) (Formerly: Improved Vector Tent Traps): Will transition from PE 0603807 (Medical Systems Advanced Development) / Project 836 (Field Medical Systems Advanced Development). Will complete developmental and user testing of the IFVT. Soldier Optimization Decision Aids (SODA): Will develop and conduct Independent Validation and Verification and limited user testing of the Cold Weather Ensemble Decision Aid and Heat Strain Decision Aid; and prepare for networkiness certification and platform integration in collaboration with PEO Soldier for the Nett Warrior Platform. Hard-Walled Shelter Modernization (Radiation Panel): Will complete developmental and user testing of the Rigid Wall Shelter transportation and vibration modifications.</p> <p><b>FY 2018 Plans:</b><br/>           Modernization of medical equipment sets: Will evaluate the Field Hospital waste water collection system, vector sampling devices, air sampling products, and other commercial items for medical equipment sets. Airworthiness Testing: Will continue to conduct airworthiness testing for Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation. Per Army Regulation 70-62, Airworthiness Qualification of Aircraft Systems, all "carry-on" equipment, to include medical devices, must have an Airworthiness Release. Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package and CASEVAC: Will continue to collaborate with Program Executive Office Ground Combat Systems for the implementation of the MES and MEP in Initial Operational Test and Evaluation of Armored Multipurpose Vehicle (AMPV). Will collaborate with PEO Combat Support/Combat Service Support for implementation of the CASEVAC system for the JLTV. Waste Treatment System for the CSH: Will complete development and incorporate changes to the waste treatment system based upon testing for re-test. IFVT (Formerly: Improved Vector Tent Traps): Will collaborate with the Armed Forces Pest Management</p> |  |  |                       |  |                |



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| <b>Appropriation/Budget Activity</b><br>2040 / 5  | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | <b>Project (Number/Name)</b><br>832 / <i>Field Medical Systems Engineering Development</i> |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>   |  | <b>FY 2016</b>   | <b>FY 2017</b> |
| Board for adoption of the Improved Flying Vector Trap as a Department of Defense (DoD) standardized product. SODA: Will transition the Cold Weather Ensemble Decision Aid and the Heat Strain Decision Aid to Program Executive Office Soldier. Will develop and conduct Independent Validation and Verification and limited user testing of the Environmental Hazards App and Mobility Decision Aids.  |  |  |                |
| <b>Title:</b> Field Medical Systems Engineering Development -PM Neurotrauma & Psychological Health<br><b>Description:</b> This effort funds systems engineering development of medical products managed by Program Manager Neurotrauma & Psychological Health for enhanced combat casualty care and follow-on care, including rehabilitation.<br><b>FY 2018 Plans:</b><br>Laboratory Assay for Traumatic Brain Injury (TBI) (formerly TBI Diagnostic Assay System) Increment II Point of Care Device: Will finalize the Biomarker and Platform technologies and combine the technologies into one system to conduct validation studies. |  | -  | -              |
| <b>Accomplishments/Planned Programs Subtotals</b>   |  | 23.119   | 24.812         |
| <b>C. Other Program Funding Summary (\$ in Millions)</b>  |  |  |                |
| N/A   |  |  |                |
| <b>Remarks</b>  |  |  |                |
| <b>D. Acquisition Strategy</b>  |  |  |                |
| Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.  |  |  |                |
| <b>E. Performance Metrics</b>   |  |  |                |
| N/A   |  |  |                |

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|---|-----------------------------------|---|--------------------|----------------|-------------------|---|-------------------|---------------------|-------------------|--------------------|-------------------|---|-------------------------|-------------------|---------------------------------|
| <b>Exhibit R-3, RDT&amp;E Project Cost Analysis: FY 2018 Army</b> |                                   |   |                    |                |                   |   |                   |                     |                   |                    |                   | <b>Date: May 2017</b>   |                         |                   |                                 |
| <b>Appropriation/Budget Activity</b><br>2040 / 5                  |                                   |   |                    |                |                   | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |                   |                     |                   |                    |                   | <b>Project (Number/Name)</b><br>832 / Field Medical Systems Engineering Development |                         |                   |                                 |
| <b>Management Services (\$ in Millions)</b>                       |                                   |   |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>  |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>   | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>   | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development Management Services Cost              | Various                           | Various : Various   | 30.202             | 1.867          |                   | 3.917   |                   | 3.724               |                   | -                  |                   | 3.724   | Continuing              | Continuing        | Continuing                      |
| <b>Subtotal</b>   |                                   |   | 30.202             | 1.867          |                   | 3.917   |                   | 3.724               |                   | -                  |                   | 3.724   | -                       | -                 | -                               |
| <b>Product Development (\$ in Millions)</b>                       |                                   |   |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>  |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>   | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>   | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Freeze-dried Human Plasma   | Various                           | HemCon Medical Technologies, Inc. : Tigard OR   | 32.750             | 0.033          |                   | -   |                   | -                   |                   | -                  |                   | -   | Continuing              | Continuing        | Continuing                      |
| 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   | 5.242              | 1.028          |                   | -   |                   | 2.206               |                   | -                  |                   | 2.206   | 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  | 2.984              | 0.309          |                   | 1.220   |                   | 4.417               |                   | -                  |                   | 4.417   | Continuing              | Continuing        | Continuing                      |
| Cryopreserved Platelets   | Various                           | Multiple DoD activities and Dartmouth Hitchcock Med Ctr : North Potomac, MD               | 14.362             | -              |                   | -   |                   | -                   |                   | -                  |                   | -   | Continuing              | Continuing        | Continuing                      |
| Cryopreserved Platelets   | Various                           | TBD : TBD   | 1.450              | 0.425          |                   | -   |                   | -                   |                   | -                  |                   | -   | 0.000                   | 1.875             | 0.000                           |
| Intracellular Hemorrhage Treatment                                | TBD                               | TBD : TBD   | 0.000              | 0.600          |                   | -   |                   | -                   |                   | -                  |                   | -   | 0.000                   | 0.600             | 0.000                           |

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| Exhibit R-3, RDT&E Project Cost Analysis: FY 2018 Army                              |                              |  |                |         |               |   |               |                 |               |   |               | Date: May 2017   |                     |               |                                |
|---|------------------------------|--|----------------|---------|---------------|---|---------------|-----------------|---------------|---|---------------|------------------|---------------------|---------------|--------------------------------|
| Appropriation/Budget Activity<br>2040 / 5   |                              |  |                |         |               | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |               |                 |               | Project (Number/Name)<br>832 / Field Medical Systems Engineering<br>Development |               |                  |                     |               |                                |
| Product Development (\$ in Millions)  |                              |  |                | FY 2016 |               | FY 2017   |               | FY 2018<br>Base |               | FY 2018<br>OCO  |               | FY 2018<br>Total |                     |               |                                |
| Cost Category Item  | Contract<br>Method<br>& Type | Performing<br>Activity & Location                      | Prior<br>Years | Cost    | Award<br>Date | Cost  | Award<br>Date | Cost            | Award<br>Date | Cost  | Award<br>Date | Cost             | Cost To<br>Complete | Total<br>Cost | Target<br>Value of<br>Contract |
| TBI Diagnostic Assay<br>System - Increment II<br>(benchtop/POC/ Bandits)            | Various                      | Banyan BioMarkers,<br>Inc : Alachua, FL                | 0.373          | -       |               | -   |               | -               |               | -   |               | -                | 0.000               | 0.373         | 0.000                          |
| Noninvasive<br>Neurodiagnostics   | TBD                          | TBD : TBD  | 2.647          | -       |               | -   |               | -               |               | -   |               | -                | 0.000               | 2.647         | 0.000                          |
| Impedance Threshold<br>Device for the Treatment<br>of Traumatic Brain Injury        | TBD                          | Advance Circulatory<br>Systems Inc. :<br>Roseville, MN | 0.335          | 4.052   |               | -   |               | -               |               | -   |               | -                | 0.000               | 4.387         | 0.000                          |
| Pre-Hospital Medical<br>Informatics Transport<br>(Ground Transport<br>Telemedicine) | TBD                          | TBD : TBD  | 0.950          | 1.166   |               | 4.629   |               | -               |               | -   |               | -                | 0.000               | 6.745         | 0.000                          |
| Advanced wound care   | Various                      | TBD : TBD  | 0.000          | -       |               | 1.594   |               | -               |               | -   |               | -                | 0.000               | 1.594         | 0.000                          |
| Junction Noncompressible<br>Hemorrhage  | TBD                          | RevMedX Inc :<br>Wilsonville OR                        | 0.000          | -       |               | 1.550   |               | -               |               | -   |               | -                | 0.000               | 1.550         | 0.000                          |
| Laboratory Assay for<br>Traumatic Brain Injury                                      | C/Various                    | Abbott Laboratories :<br>Chicago, IL                   | 0.000          | -       |               | -   |               | 3.910           |               | -   |               | 3.910            | Continuing          | Continuing    | Continuing                     |
| Subtotal  |                              |  | 79.333         | 7.613   |               | 8.993   |               | 10.533          |               | -   |               | 10.533           | -                   | -             | -                              |
| Support (\$ in Millions)  |                              |  |                | FY 2016 |               | FY 2017   |               | FY 2018<br>Base |               | FY 2018<br>OCO  |               | FY 2018<br>Total |                     |               |                                |
| Cost Category Item  | Contract<br>Method<br>& Type | Performing<br>Activity & Location                      | Prior<br>Years | Cost    | Award<br>Date | Cost  | Award<br>Date | Cost            | Award<br>Date | Cost  | Award<br>Date | Cost             | Cost To<br>Complete | Total<br>Cost | Target<br>Value of<br>Contract |
| Regulatory Support  | Various                      | Clinical Research<br>Management, Inc., :<br>Various    | 6.216          | 0.307   |               | 1.960   |               | 0.307           |               | -   |               | 0.307            | Continuing          | Continuing    | Continuing                     |
| Medical Product<br>Development Support Cost   | Various                      | Various : Various                                      | 8.661          | 1.548   |               | -   |               | 1.829           |               | -   |               | 1.829            | Continuing          | Continuing    | Continuing                     |
| Medical Equipment Sets<br>Development   | Various                      | Various : Various                                      | 2.670          | -       |               | -   |               | -               |               | -   |               | -                | 0.000               | 2.670         | 0.000                          |
| Subtotal  |                              |  | 17.547         | 1.855   |               | 1.960   |               | 2.136           |               | -   |               | 2.136            | -                   | -             | -                              |
|   |                              |  |                |         |               |   |               |                 |               |   |               |                  |                     |               |                                |

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|--|------------------------------|-----------------------------------|----------------|---------|---------------|---|---------------|-----------------|---------------|---|---------------|------------------|---------------------|---------------|--------------------------------|
| Exhibit R-3, RDT&E Project Cost Analysis: FY 2018 Army |                              |                                   |                |         |               |   |               |                 |               |   |               | Date: May 2017   |                     |               |                                |
| Appropriation/Budget Activity<br>2040 / 5              |                              |                                   |                |         |               | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |               |                 |               | Project (Number/Name)<br>832 / Field Medical Systems Engineering<br>Development |               |                  |                     |               |                                |
| Test and Evaluation (\$ in Millions)                   |                              |                                   |                | FY 2016 |               | FY 2017   |               | FY 2018<br>Base |               | FY 2018<br>OCO  |               | FY 2018<br>Total |                     |               |                                |
| Cost Category Item                                     | Contract<br>Method<br>& Type | Performing<br>Activity & Location | Prior<br>Years | Cost    | Award<br>Date | Cost  | Award<br>Date | Cost            | Award<br>Date | Cost  | Award<br>Date | Cost             | Cost To<br>Complete | Total<br>Cost | Target<br>Value of<br>Contract |
| Medical Product<br>Development T&E Cost                | Various                      | Various : Various                 | 14.408         | 1.615   |               | -   |               | 1.481           |               | -   |               | 1.481            | Continuing          | Continuing    | Continuing                     |
| Cryopreserved Platelets                                | TBD                          | TBD : TBD                         | 2.893          | 6.101   |               | 4.865   |               | 3.260           |               | -   |               | 3.260            | 0.000               | 17.119        | 0.000                          |
| Medical Equipment Sets<br>Development                  | Various                      | Various : Various                 | 1.206          | -       |               | -   |               | 0.650           |               | -   |               | 0.650            | 0.000               | 1.856         | 0.000                          |
| Freeze Dried Plasma                                    | C/CPFF                       | TBD : TBD                         | 2.657          | 4.068   |               | 3.797   |               | 3.028           |               | -   |               | 3.028            | 0.000               | 13.550        | 0.000                          |
| Subtotal   |                              |                                   | 21.164         | 11.784  |               | 8.662   |               | 8.419           |               | -   |               | 8.419            | -                   | -             | -                              |
|  |                              |                                   | Prior<br>Years | FY 2016 |               | FY 2017   |               | FY 2018<br>Base |               | FY 2018<br>OCO  |               | FY 2018<br>Total | Cost To<br>Complete | Total<br>Cost | Target<br>Value of<br>Contract |
| Project Cost Totals                                    |                              |                                   | 148.246        | 23.119  |               | 23.532  |               | 24.812          |               | -   |               | 24.812           | -                   | -             | -                              |
| Remarks  |                              |                                   |                |         |               |   |               |                 |               |   |               |                  |                     |               |                                |

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| Exhibit R-4, RDT&E Schedule Profile: FY 2018 Army                         |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   | Date: May 2017                                      |         |   |   |   |         |   |   |   |  |
|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|--|
| Appropriation/Budget Activity   |         |   |   |   |         |   |   |   |         | R-1 Program Element (Number/Name)   |   |   |         |   |   |   |         |   |   | Project (Number/Name)                               |         |   |   |   |         |   |   |   |  |
| 2040 / 5  |         |   |   |   |         |   |   |   |         | PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |   |   |         |   |   |   |         |   |   | 832 / Field Medical Systems Engineering Development |         |   |   |   |         |   |   |   |  |
| Event Name  | FY 2016 |   |   |   | FY 2017 |   |   |   | FY 2018 |   |   |   | FY 2019 |   |   |   | FY 2020 |   |   |   | FY 2021 |   |   |   | FY 2022 |   |   |   |  |
|   | 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 |  |
| Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies           |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| Cryopreserved Platelets (CPP) Phase III clinical studies                  |         |   |   |   | Phase 2 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| (1) Cryopreserved Platelets (CPP) Milestone C                             |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| Freeze-dried Plasma (FDP) Phase I safety clinical studies                 |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   | Phase 3 |   |   |   |         |   |   |   |  |
| FDP Phase 2 efficacy clinical studies                                     |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| (2) FDP MS-B  |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| (3) FDP MS-C  |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| (4) Compartment Syndrome Pressure Device MS-A                             |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| (5) Noninvasive Neurodiagnostics MS-C                                     |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |
| Laboratory Assay for TBI Increment !! Point of Care Device Clinical Trial |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |  |

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| <b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> FY 2018 Army |  |  | <b>Date:</b> May 2017 |
| <b>Appropriation/Budget Activity</b><br>2040 / 5              | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev | <b>Project (Number/Name)</b><br>832 / Field Medical Systems Engineering<br>Development |                       |

## Schedule Details

| Events  | Start   |      | End     |      |
|---|---------|------|---------|------|
|   | Quarter | Year | Quarter | Year |
| Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies           | 3       | 2015 | 4       | 2018 |
| Cryopreserved Platelets (CPP) Phase III clinical studies                  | 4       | 2017 | 3       | 2021 |
| Cryopreserved Platelets (CPP) Milestone C                                 | 2       | 2020 | 2       | 2020 |
| 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 |
| Compartment Syndrome Pressure Device MS-A                                 | 2       | 2018 | 2       | 2018 |
| Noninvasive Neurodiagnostics MS-C   | 4       | 2019 | 4       | 2019 |
| Laboratory Assay for TBI Increment !! Point of Care Device Clinical Trial | 1       | 2020 | 4       | 2021 |

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| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army |                |         |         |                 |   |                  |         |         |   | Date: May 2017 |                     |               |
|---|----------------|---------|---------|-----------------|---|------------------|---------|---------|---|----------------|---------------------|---------------|
| Appropriation/Budget Activity<br>2040 / 5               |                |         |         |                 | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |                  |         |         | Project (Number/Name)<br>849 / Infec Dis Drug/Vacc Ed |                |                     |               |
| COST (\$ in Millions)                                   | Prior<br>Years | FY 2016 | FY 2017 | FY 2018<br>Base | FY 2018<br>OCO  | FY 2018<br>Total | FY 2019 | FY 2020 | FY 2021   | FY 2022        | Cost To<br>Complete | Total<br>Cost |
| 849: Infec Dis Drug/Vacc Ed                             | -              | 15.461  | 12.922  | 13.243          | -   | 13.243           | 14.873  | 16.466  | 16.899  | 17.390         | Continuing          | Continuing    |
| Quantity of RDT&E Articles                              | -              | -       | -       | -               | -   | -                | -       | -       | -   | -              |                     |               |

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

This Project funds development of candidate medical countermeasures for militarily relevant infectious diseases. These products fall within four major areas: vaccines, drugs, diagnostic kits/devices, and determining if insects are infected with pathogenic organisms capable of infecting service members' insect control/preventive medicine measures to limit exposure and disease transmission. It funds research that supports conclusive human clinical trials for large-scale human effectiveness (capacity to produce a desired size of an effect under ideal or optimal conditions) testing, expanded human safety clinical trials, long-term animal studies, 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 successfully complete a series of clinical trials that are required and regulated by the United States (U.S.) Food and Drug Administration (FDA). FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. 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 Africa Command, Central Command, European Command, Southern Command, and Pacific Command areas are at the top of the infectious diseases requirements list.

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

|   | <b>FY 2016</b> | <b>FY 2017</b> | <b>FY 2018</b> |
|---|----------------|----------------|----------------|
| <b>Title:</b> Infectious Disease Drug and Vaccine Engineering Development   | 15.461         | 12.922         | 13.243         |
| <b>Description:</b> Funding for research and development efforts for Drugs and Vaccines.  |                |                |                |
| <b>FY 2016 Accomplishments:</b><br>Dengue Tetravalent Vaccine (DTV): Complete Phase 3 (safety, efficacy, and dosing) pivotal clinical trials and adult/military-specific indication studies. Submit the master file (product documentation) for endemic countries to the FDA. Complete Milestone C package. Develop Biologic License Application (BLA) for U.S. Licensure. Final reports near completion for BLA submission in Fiscal Year (FY) 17 to the FDA. Commercial Partner to produce validation lots at their dedicated manufacturing facility. Next Generation Malaria Prophylaxis: Continue to complete New Drug Application preparatory work for filing with the FDA. Initiate a retinal safety study in 2016 and prepare the protocols for required soldier specific studies that need to be completed. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Complete the New Drug Application submission package and submit to the FDA for approval. Validate the manufacturing process for commercial production of the cream. Continue the expanded access and treatment protocols through FY 16. Antimalarial Drug, Artesunate Intravenous: Support FDA inquiries during the review process of the New Drug Application. Work with the commercial partner to support marketing and distribution plans for the |                |                |                |

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|--|--|---|----------------|---|----------------|
| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army  |  |   | Date: May 2017 |   |                |
| Appropriation/Budget Activity<br>2040 / 5  |  | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev |                | Project (Number/Name)<br>849 / Infec Dis Drug/Vacc Ed |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  |  |   | <b>FY 2016</b> | <b>FY 2017</b>  | <b>FY 2018</b> |
| <p>drug. Preventive Medicine advanced detection devices: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). Preventive Medicine advanced pesticides: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). Preventive Medicine spatial repellents: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). Preventive Medicine arthropod collection devices: These products fall into the category military operational requirements and are Commercial-Off-The-Shelf (COTS). Diagnostic products: Delays in the previous year's transition for infectious disease diagnostic products due to product maturity. Begin field testing and evaluation of several product candidates to include: Scrub Typhus, Rickettsiae, and Sand Fly Fever. Dengue Vaccine Block II: Prepare for human challenge efforts to show vaccine efficacy and animal studies to determine correlates of immunity in preparation for Phase III (safety, efficacy, and dosing) clinical trials. Arthropod Control/Surveillance: Begin field testing and evaluation of a Dengue Rapid Diagnostic.</p> <p><b>FY 2017 Plans:</b></p> <p>DTV: Will continue to fund Block I Dengue Tetravalent Vaccine until FY18. Funding will cover the additional two-year volunteer follow-up and data analysis on pivotal Phase 3 safety and effectiveness clinical trials as well as analysis and submission of adult military/traveler phase 2 (safety and efficacy) data aimed toward FDA licensure (Key Performance Parameter) . Will continue to work with the commercial partner to support FDA submissions, marketing and distribution plans for the vaccine. Will start planning for potential Milestone (MS) C in FY17; fielding anticipated FY18. Next Generation Malaria Prophylaxis: Will continue to complete New Drug Application preparatory work for filing with the FDA. Will continue the retinal safety study started in FY16 and will prepare the protocols for required soldier specific studies that need to be completed. Will start planning for potential MS C in FY17. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): The planned submission of the New Drug Application (NDA) did not occur in FY16 due to the loss of a manufacturing subcontractor. The NDA submission package will be completed and submitted to the FDA for approval in FY17. The manufacturing process will be validated in preparation for commercial production of the cream. The expanded access treatment protocol will continue through FY 17. Antimalarial Drug, Artesunate Intravenous: Will continue to support FDA inquiries during the review process of the New Drug Application. Will continue to work with the commercial partner to support marketing and distribution plans for the drug. Infectious Disease Diagnostic products: In FY17 products within this area will move to the Rapid Diagnostic and Detection Devices. Development (clinical performance testing) of a rapid human dengue diagnostic device will be anticipated. Dengue Vaccine Block II: Development of additional dengue human challenge strains will continue. Evaluation of vaccine candidates through performance of dengue human challenge studies in preparation for Phase III (safety, efficacy, and dosing) clinical trials. Rapid Diagnostic and Detection Devices: Will continue field testing and evaluation of several product candidates to include: dengue, chikungunya and leptospirosis.</p> <p><b>FY 2018 Plans:</b></p> <p>DTV: Will Fund Block I Dengue Tetravalent Vaccine through FY18 to complete two-year study subject follow-up required by Thai Ministry of Public Health. Will continue military-specific clinical trials that begin in FY17. Next Generation Malaria Prophylaxis: Will continue to complete New Drug Application preparatory work for filing with the FDA. Will continue the retinal (eye) safety study</p> |  |   |                |   |                |



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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> FY 2018 Army   |  | <b>Date:</b> May 2017   |                |
| <b>Appropriation/Budget Activity</b><br>2040 / 5   | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i> | <b>Project (Number/Name)</b><br>849 / <i>Infec Dis Drug/Vacc Ed</i> |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  |  | <b>FY 2016</b>  | <b>FY 2017</b> |
| started in FY16 and prepare the protocols for required soldier specific studies. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Will conduct stability testing of the registration lots of the drug product. Prepare for potential FDA requirements for post-marketing surveillance or clinical trials to gather additional information about a product's safety, effectiveness, or optimal use. Antimalarial Drug, Artesunate Intravenous: Will support the FDA's inquiries during the review process of the New Drug Application. Work with the commercial partner to support commercial marketing and distribution plans for the drug. Dengue Vaccine Block II: Continue development of additional dengue human challenge strains. Will evaluate vaccine candidates using dengue human challenge studies in preparation for pivotal safety, effectiveness, and dosing (Phase III) clinical trials. Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): Will continue field testing and evaluation of several product candidates to include: dengue and chikungunya. |  |   |                |
| <b>Accomplishments/Planned Programs Subtotals</b>  |  | 15.461  | 12.922         |
| <b>C. Other Program Funding Summary (\$ in Millions)</b><br>N/A  |  |   |                |
| <b>Remarks</b>   |  |   |                |
| <b>D. Acquisition Strategy</b><br>Test and evaluate in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.   |  |   |                |
| <b>E. Performance Metrics</b><br>N/A   |  |   |                |

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|---|-----------------------------------|--|--------------------|----------------|-------------------|---|-------------------|---------------------|-------------------|--------------------|-------------------|--|-------------------------|-------------------|---------------------------------|
| <b>Exhibit R-3, RDT&amp;E Project Cost Analysis: FY 2018 Army</b> |                                   |  |                    |                |                   |   |                   |                     |                   |                    |                   | <b>Date: May 2017</b>  |                         |                   |                                 |
| <b>Appropriation/Budget Activity</b><br>2040 / 5                  |                                   |  |                    |                |                   | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |                   |                     |                   |                    |                   | <b>Project (Number/Name)</b><br>849 / Infec Dis Drug/Vacc Ed |                         |                   |                                 |
| <b>Management Services (\$ in Millions)</b>                       |                                   |  |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>              | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development Management Services Cost              | Various                           | Various : Various                                      | 19.146             | 0.727          |                   | 0.792   |                   | 0.877               |                   | -                  |                   | 0.877  | Continuing              | Continuing        | Continuing                      |
| Medical Product Development Management Services Cost              | C/CPFF                            | General Dynamics Information Technology : Frederick MD | 1.012              | 2.756          |                   | 3.153   |                   | 3.212               |                   | -                  |                   | 3.212  | 0.000                   | 10.133            | 0.000                           |
| <b>Subtotal</b>   |                                   |  | 20.158             | 3.483          |                   | 3.945   |                   | 4.089               |                   | -                  |                   | 4.089  | -                       | -                 | -                               |
| <b>Product Development (\$ in Millions)</b>                       |                                   |  |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>              | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development Cost                                  | Various                           | Various : Various                                      | 34.044             | 2.007          |                   | 1.000   |                   | 0.963               |                   | -                  |                   | 0.963  | Continuing              | Continuing        | Continuing                      |
| Topical Antileishmanial Drug                                      | TBD                               | TBD : TBD  | 2.400              | -              |                   | -   |                   | -                   |                   | -                  |                   | -  | 0.000                   | 2.400             | 0.000                           |
| Topical Antileishmanial Drug                                      | C/TBD                             | Advantar Laboratories, INC : TBD                       | 1.229              | 0.662          |                   | 0.316   |                   | 0.586               |                   | -                  |                   | 0.586  | 0.000                   | 2.793             | 0.000                           |
| Dengue Tetravalent Vaccine  | TBD                               | TBD : TBD  | 1.399              | 0.648          |                   | -   |                   | -                   |                   | -                  |                   | -  | 0.000                   | 2.047             | 0.000                           |
| Hemorrhagic Fever W/ Renal Syndrome                               | C/TBD                             | TBD : TBD  | 0.000              | 1.000          |                   | -   |                   | -                   |                   | -                  |                   | -  | 0.000                   | 1.000             | 0.000                           |
| <b>Subtotal</b>   |                                   |  | 39.072             | 4.317          |                   | 1.316   |                   | 1.549               |                   | -                  |                   | 1.549  | -                       | -                 | -                               |
| <b>Support (\$ in Millions)</b>                                   |                                   |  |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>              | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development Support Cost                          | Various                           | Various : Various                                      | 17.877             | 1.503          |                   | -   |                   | -                   |                   | -                  |                   | -  | Continuing              | Continuing        | Continuing                      |

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|---|-----------------------------------|---|--------------------|----------------|-------------------|---|-------------------|---------------------|-------------------|--------------------|-------------------|--|-------------------------|-------------------|---------------------------------|
| <b>Exhibit R-3, RDT&amp;E Project Cost Analysis: FY 2018 Army</b> |                                   |   |                    |                |                   |   |                   |                     |                   |                    |                   | <b>Date: May 2017</b>  |                         |                   |                                 |
| <b>Appropriation/Budget Activity</b><br>2040 / 5                  |                                   |   |                    |                |                   | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |                   |                     |                   |                    |                   | <b>Project (Number/Name)</b><br>849 / Infec Dis Drug/Vacc Ed |                         |                   |                                 |
| <b>Support (\$ in Millions)</b>                                   |                                   |   |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>       | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development Support Cost                          | PO                                | Clinical Research Management, In : Hinckley, OH | 3.168              | 0.287          |                   | 1.308   |                   | 0.976               |                   | -                  |                   | 0.976  | 0.000                   | 5.739             | 0.000                           |
| <b>Subtotal</b>   |                                   |   | 21.045             | 1.790          |                   | 1.308   |                   | 0.976               |                   | -                  |                   | 0.976  | -                       | -                 | -                               |
| <b>Test and Evaluation (\$ in Millions)</b>                       |                                   |   |                    | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   |                         |                   |                                 |
| <b>Cost Category Item</b>   | <b>Contract Method &amp; Type</b> | <b>Performing Activity &amp; Location</b>       | <b>Prior Years</b> | <b>Cost</b>    | <b>Award Date</b> | <b>Cost</b>   | <b>Award Date</b> | <b>Cost</b>         | <b>Award Date</b> | <b>Cost</b>        | <b>Award Date</b> | <b>Cost</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| Medical Product Development T&E Cost                              | Various                           | Various : Various                               | 38.996             | 2.725          |                   | 3.593   |                   | 4.067               |                   | -                  |                   | 4.067  | Continuing              | Continuing        | Continuing                      |
| Dengue Tetravalent Vaccine  | TBD                               | WRAIR/AFRIMS : Silver Spring MD                 | 0.000              | -              |                   | 0.881   |                   | 0.450               |                   | -                  |                   | 0.450  | 0.000                   | 1.331             | 0.000                           |
| Dengue Tetravalent Vaccine  | C/TBD                             | TBD : TBD                                       | 0.000              | -              |                   | 1.879   |                   | 2.112               |                   | -                  |                   | 2.112  | 0.000                   | 3.991             | 0.000                           |
| Product Development of Dengue Tetravalent Vaccine                 | Various                           | TBD : TBD                                       | 1.384              | 3.146          |                   | -   |                   | -                   |                   | -                  |                   | -  | 0.000                   | 4.530             | 0.000                           |
| <b>Subtotal</b>   |                                   |   | 40.380             | 5.871          |                   | 6.353   |                   | 6.629               |                   | -                  |                   | 6.629  | -                       | -                 | -                               |
|   |                                   |   | <b>Prior Years</b> | <b>FY 2016</b> |                   | <b>FY 2017</b>  |                   | <b>FY 2018 Base</b> |                   | <b>FY 2018 OCO</b> |                   | <b>FY 2018 Total</b>   | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| <b>Project Cost Totals</b>  |                                   |   | 120.655            | 15.461         |                   | 12.922  |                   | 13.243              |                   | -                  |                   | 13.243   | -                       | -                 | -                               |
| <b>Remarks</b>  |                                   |   |                    |                |                   |   |                   |                     |                   |                    |                   |  |                         |                   |                                 |

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Exhibit R-4, RDT&E Schedule Profile: FY 2018 Army

Date: May 2017

Appropriation/Budget Activity

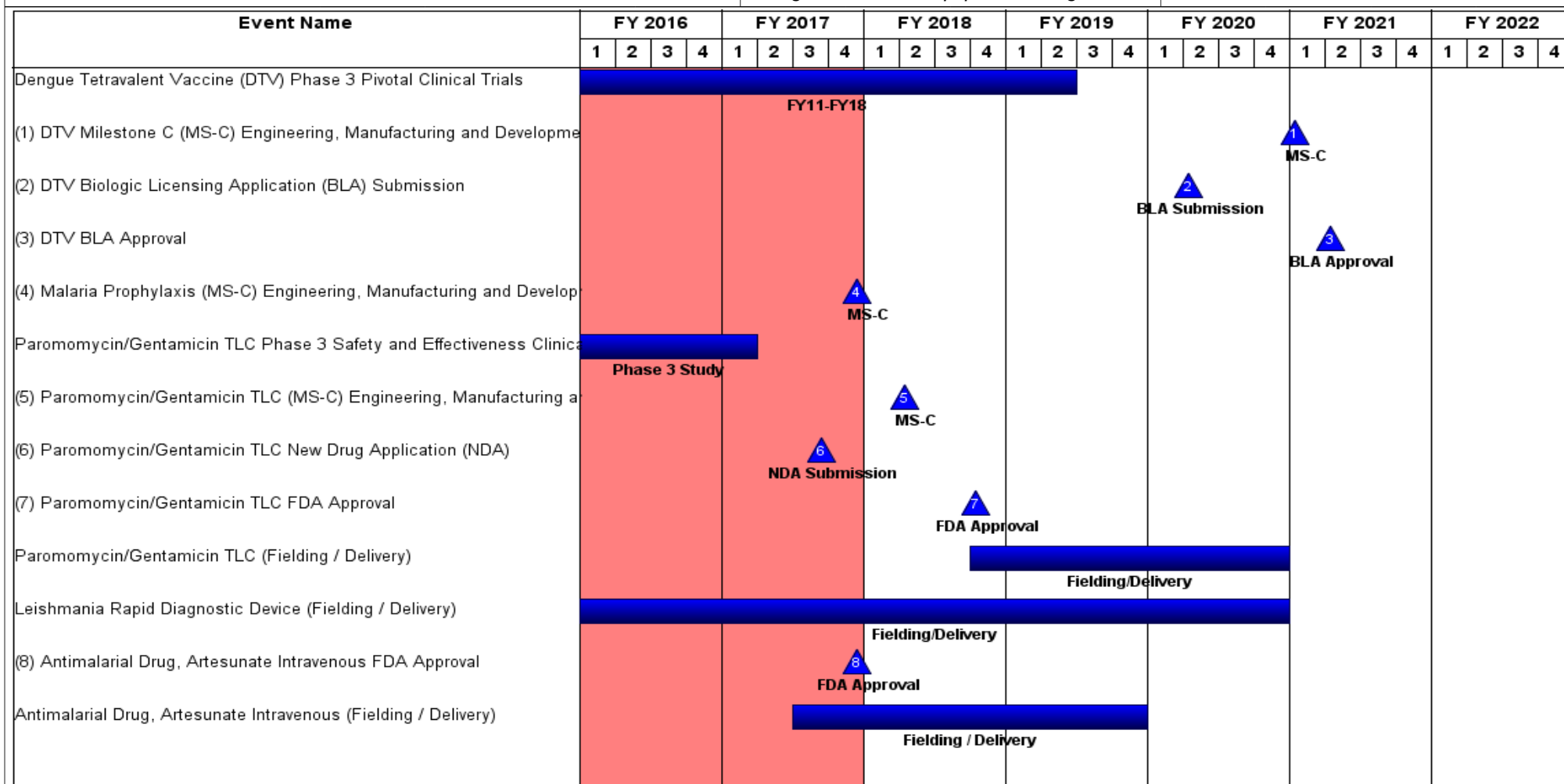
2040 / 5

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



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PE 0604807A: *Medical Materiel/Medical Biological Defe...*  
Army

R-1 Line #107

| R-1 Program Element (Number/Name) |
|-----------------------------------|
|-----------------------------------|

PE 0604807A / Medical Materiel/Medical  
Biological Defense Equipment - Eng Dev

849 / *Infec Dis Drug/Vacc Ed*

PE 0604807A: Medical Materiel/Medical Biological Defe...  
 Army

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R-1 Line #107

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|---|--|--|-----------------------|
| <b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> FY 2018 Army |  |  | <b>Date:</b> May 2017 |
| <b>Appropriation/Budget Activity</b><br>2040 / 5              | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev | <b>Project (Number/Name)</b><br>849 / Infec Dis Drug/Vacc Ed |                       |

**Schedule Details**

| <b>Events</b>  | <b>Start</b>   |             | <b>End</b>     |             |
|--|----------------|-------------|----------------|-------------|
|  | <b>Quarter</b> | <b>Year</b> | <b>Quarter</b> | <b>Year</b> |
| Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials               | 1              | 2011        | 2              | 2019        |
| DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review | 1              | 2021        | 1              | 2021        |
| 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              | 2017        | 4              | 2017        |
| Paromomycin/Gentamicin TLC Phase 3 Safety and Effectiveness Clinical Trial     | 1              | 2016        | 1              | 2017        |
| Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development   | 2              | 2018        | 2              | 2018        |
| Paromomycin/Gentamicin TLC New Drug Application (NDA)                          | 3              | 2017        | 3              | 2017        |
| Paromomycin/Gentamicin TLC FDA Approval  | 4              | 2018        | 4              | 2018        |
| Paromomycin/Gentamicin TLC (Fielding / Delivery)                               | 4              | 2018        | 4              | 2020        |
| Leishmania Rapid Diagnostic Device (Fielding / Delivery)                       | 1              | 2015        | 4              | 2020        |
| Antimalarial Drug, Artesunate Intravenous FDA Approval                         | 4              | 2017        | 4              | 2017        |
| Antimalarial Drug, Artesunate Intravenous (Fielding / Delivery)                | 3              | 2017        | 4              | 2019        |
| 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        |
| Antimalarial Drug, Artesunate Intravenous New Drug Application (MS-C)          | 4              | 2016        | 4              | 2016        |

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|---|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> FY 2018 Army  |                    |                |                |                     |   |                      |                |                |   | <b>Date:</b> May 2017 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 5  |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev |                      |                |                | <b>Project (Number/Name)</b><br>VS8 / MEDEVAC Mission Equipment Package (MEP) - End Dev |                       |                         |                   |
| <b>COST (\$ in Millions)</b>  | <b>Prior Years</b> | <b>FY 2016</b> | <b>FY 2017</b> | <b>FY 2018 Base</b> | <b>FY 2018 OCO</b>  | <b>FY 2018 Total</b> | <b>FY 2019</b> | <b>FY 2020</b> | <b>FY 2021</b>  | <b>FY 2022</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| VS8: MEDEVAC Mission Equipment Package (MEP) - End Dev  | -                  | 0.383          | 0.113          | 0.000               | -   | 0.000                | 0.000          | 0.000          | 0.000   | 0.000                 | Continuing              | Continuing        |
| Quantity of RDT&E Articles  | -                  | -              | -              | -                   | -   | -                    | -              | -              | -   | -                     |                         |                   |
| <b>A. Mission Description and Budget Item Justification</b><br><p>Original models of Army Black Hawk medical evacuation (MEDEVAC) helicopters continue to play a major role in maintaining high United States (U.S.) troop survival rates in Iraq and Afghanistan by evacuating wounded troops in less than one-hour. In 2009, a 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 Army Medical Department (AMEDD) accepted life-cycle management of the MEDEVAC MEP from Program Executive Office (PEO) Aviation. In order to achieve required operational capability and enhance commonality across the MEDEVAC fleet, the MEDEVAC Mission Essential Program (MEP) upgrades and retrofits the 256 MEDEVAC legacy helicopters to achieve the medical capability provided by the HH-60M, which is factory built for the MEDEVAC mission.</p> |                    |                |                |                     |   |                      |                |                |   |                       |                         |                   |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>   |                    |                |                |                     |   |                      |                |                | <b>FY 2016</b>  | <b>FY 2017</b>        | <b>FY 2018</b>          |                   |
| <b>Title:</b> Interim MEDEVAC Mission Support System (IMMSS)<br><br><b>Description:</b> Interim MEDEVAC Mission Support System (IMMSS) - Patient Handling System for safely handling patient through a system of seats, patient litters etc.<br><br><b>FY 2016 Accomplishments:</b><br>Any modifications to the IMMSS that are made based on new paramedic skills will require validation and verification. Develop plans for required validation and verification to address the new paramedic skills.<br><br><b>FY 2017 Plans:</b><br>Interim MEDEVAC Mission Support System (IMMSS): Will complete validation study to verify IMMSS supports Medical Evacuation En Route Care.   |                    |                |                |                     |   |                      |                |                | 0.383   | 0.113                 | -                       |                   |
| <b>Accomplishments/Planned Programs Subtotals</b>   |                    |                |                |                     |   |                      |                |                | 0.383   | 0.113                 | -                       |                   |
| <b>C. Other Program Funding Summary (\$ in Millions)</b><br>N/A<br><b>Remarks</b>   |                    |                |                |                     |   |                      |                |                |   |                       |                         |                   |
| <b>D. Acquisition Strategy</b><br>Develop in-house or industrial prototypes in government-managed programs to meet military MEDEVAC and regulatory requirements for production and fielding.  |                    |                |                |                     |   |                      |                |                |   |                       |                         |                   |

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|---|---|---|
| Exhibit R-2A, RDT&E Project Justification: FY 2018 Army |   | Date: May 2017  |
| Appropriation/Budget Activity<br>2040 / 5               | R-1 Program Element (Number/Name)<br>PE 0604807A / Medical Materiel/Medical<br>Biological Defense Equipment - Eng Dev | Project (Number/Name)<br>VS8 / MEDEVAC Mission Equipment<br>Package (MEP) - End Dev |
| E. Performance Metrics<br>N/A                           |   |   |