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**Exhibit R-2, RDT&E Budget Item Justification: PB 2022 Army** **Date:** May 2021

| <b>Appropriation/Budget Activity</b>   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b> |                      |                |                |                |                |                         |                   |
|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|----------------|----------------|-------------------------|-------------------|
| 2040: Research, Development, Test & Evaluation, Army / BA 4: Advanced Component Development & Prototypes (ACD&P) |                    |                |                |                     | PE 0603807A / Medical Systems - Adv Dev  |                      |                |                |                |                |                         |                   |
| <b>COST (\$ in Millions)</b>   | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>                       | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b> | <b>FY 2026</b> | <b>Cost To Complete</b> | <b>Total Cost</b> |
| Total Program Element  | -                  | 36.307         | 33.085         | 22.071              | -  | 22.071               | -              | -              | -              | -              | -                       | -                 |
| 808: DoD Drug & Vacc Ad  | -                  | 10.903         | 10.547         | 6.477               | -  | 6.477                | -              | -              | -              | -              | -                       | -                 |
| 811: Mil HIV Vac&Drug Dev  | -                  | 5.236          | 4.912          | -                   | -  | -                    | -              | -              | -              | -              | -                       | -                 |
| 836: Field Medical Systems Advanced Development  | -                  | 13.587         | 17.335         | 15.594              | -  | 15.594               | -              | -              | -              | -              | -                       | -                 |
| FF4: Counterdrug, DDR, Sys Development & Demonstration   | -                  | 0.500          | -              | -                   | -  | -                    | -              | -              | -              | -              | -                       | -                 |
| VST: MEDEVAC Mission Equipment Package (MEP) - Adv Dev   | -                  | 6.081          | 0.291          | -                   | -  | -                    | -              | -              | -              | -              | -                       | -                 |

**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. These efforts 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.

| <b>B. Program Change Summary (\$ in Millions)</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b> | <b>FY 2022 Total</b> |
|---|----------------|----------------|---------------------|--------------------|----------------------|
| Previous President's Budget                       | 36.975         | 28.520         | 37.008              | -                  | 37.008               |
| Current President's Budget                        | 36.307         | 33.085         | 22.071              | -                  | 22.071               |
| Total Adjustments                                 | -0.668         | 4.565          | -14.937             | -                  | -14.937              |
| • Congressional General Reductions                | -              | -              | -                   | -                  | -                    |
| • Congressional Directed Reductions               | -              | -              | -                   | -                  | -                    |
| • Congressional Rescissions                       | -              | -              | -                   | -                  | -                    |
| • Congressional Adds                              | -              | 5.500          | -                   | -                  | -                    |
| • Congressional Directed Transfers                | -              | -              | -                   | -                  | -                    |
| • Reprogrammings                                  | 0.500          | -              | -                   | -                  | -                    |
| • SBIR/STTR transfer                              | -1.168         | -0.935         | -                   | -                  | -                    |
| • Adjustments to Budget Years                     | -              | -              | -14.937             | -                  | -14.937              |

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**Exhibit R-2, RDT&E Budget Item Justification:** PB 2022 Army **Date:** May 2021

**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 - Adv Dev*

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

**Project:** 836: *Field Medical Systems Advanced Development*  
 Congressional Add: *Program increase - composite shelter*

Congressional Add Subtotals for Project: 836

**Project:** VS7: *MEDEVAC Mission Equipment Package (MEP) - Adv Dev*  
 Congressional Add: *Transport Telemedicine*

Congressional Add Subtotals for Project: VS7

Congressional Add Totals for all Projects

| FY 2020 | FY 2021 |
|---------|---------|
| -       | 5.500   |
| -       | 5.500   |
| 5.800   | -       |
| 5.800   | -       |
| 5.800   | 5.500   |

**Change Summary Explanation**

Needs an explanation for FY22 decrease

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|  |                    |                |                |                     |  |                      |                |                |   |                       |                         |                   |
|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |                    |                |                |                     |  |                      |                |                |   | <b>Date:</b> May 2021 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> |                      |                |                | <b>Project (Number/Name)</b><br>808 / <i>DoD Drug &amp; Vacc Ad</i> |                       |                         |                   |
| <b>COST (\$ in Millions)</b>                                       | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>   | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b>  | <b>FY 2026</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| 808: <i>DoD Drug &amp; Vacc Ad</i>                                 | -                  | 10.903         | 10.547         | 6.477               | -  | 6.477                | -              | -              | -   | -                     | -                       | -                 |
| 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. 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 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). Products from this Project will transition to PE 0604807A/Project 849 at MS B.

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

|   | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|---|----------------|----------------|----------------|
| <b>Title:</b> DoD Drug and Vaccine Advanced Development   | 10.903         | 10.547         | -              |
| <b>Description:</b> Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention, early diagnosis and accelerated recovery time. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices.   |                |                |                |
| <b>FY 2021 Plans:</b><br>Treatment for Resistant Infections ? Antifungal Drug (formerly Treatment for Resistant Infections): Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant animal models.<br><br>Malaria Prophylactic Drug ? Tafenoquine (TQ) (Formerly Next Generation Malaria Prophylaxis): Achieved Milestone C in FY 2019. Will continue the retinal (eye) safety study. Additional clinical sites were added. Address any FDA post-marketing approval requirements.<br><br>Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): The dengue assay did not transition to PE 0604807A Project 849 in FY 2019 as expected. The dengue assay will transition in FY 2020. The chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for chikungunya. |                |                |                |
| <b>FY 2021 to FY 2022 Increase/Decrease Statement:</b>  |                |                |                |

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army | <b>Date:</b> May 2021 |
|--|-----------------------|

|  |   |  |
|--|---|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>808 / DoD Drug & Vacc Ad |
|--|---|--|

| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>   | FY 2020 | FY 2021 | FY 2022 |
|---|---------|---------|---------|
| Decrease due to restructuring of R-Forms input  |         |         |         |
| <p><b>Title:</b> DoD Drug and Vaccine Advanced Development - Medical Readiness</p> <p><b>Description:</b> Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on prevention to increase medical readiness. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices</p> <p><b>FY 2022 Plans:</b><br/>Staphylococcus aureus Vaccine: Prepare for transition of a vaccine candidate from industry and begin planning for a Phase 2 safety and efficacy trial of the candidate in an endemic population and an adult military/traveler population. We will conduct market research, develop CRADA's with industry partners and initiate acquisition documentation.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>Increase due to restructuring of R-Forms input</p>  | -       | -       | 1.191   |
| <p><b>Title:</b> DoD Drug and Vaccine Advanced Development - Battlefield Care and Return to Fight</p> <p><b>Description:</b> Funding is provided for the development of candidate medical countermeasures for military relevant infectious disease focusing on early diagnosis and accelerated recovery time. Funding supports both technical evaluations and human clinical testing to assure the safety and effectiveness of drugs, vaccines, medical diagnostic kits and devices</p> <p><b>FY 2022 Plans:</b><br/>Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): Conduct initial clinical efficacy trials and manufacturing development of the Tropical Disease and Flu and Viral Infection Diseases (FLU-VID) diagnostic panels for a man-portable device.</p> <p>Treatment for Drug Resistant Battlefield Wound Infections: Will monitor technical maturity of candidate treatments for evidence of safety and efficacy in relevant animal models.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>Increase due to restructuring of R-Forms input</p> | -       | -       | 5.286   |
| <b>Accomplishments/Planned Programs Subtotals</b>   | 10.903  | 10.547  | 6.477   |

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

**Remarks**

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**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Army **Date:** May 2021

|  |  |   |
|--|--|---|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>808 / <i>DoD Drug &amp; Vacc Ad</i> |
|--|--|---|

**D. Acquisition Strategy**

Test and evaluate in-house and commercially developed products in extensive commercial partner or government-managed clinical trials to gather data required for FDA licensure ensuring government (military) requirements are met with judicious investment.

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army   |                        |   |             |   |            |         |            |                          |            |             |            | Date: May 2021 |                  |            |                          |
|--|------------------------|---|-------------|---|------------|---------|------------|--------------------------|------------|-------------|------------|----------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity  |                        |   |             | R-1 Program Element (Number/Name)       |            |         |            | Project (Number/Name)    |            |             |            |                |                  |            |                          |
| 2040 / 4   |                        |   |             | PE 0603807A / Medical Systems - Adv Dev |            |         |            | 808 / DoD Drug & Vacc Ad |            |             |            |                |                  |            |                          |
| Management Services (\$ in Millions)   |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base             |            | FY 2022 OCO |            | FY 2022 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                         | 28.830      | 2.739                                   |            | 0.267   |            | 0.312                    |            | -           |            | 0.312          | Continuing       | Continuing | Continuing               |
| Medical Product Development Management Services Cost   | PO                     | General Dynamics Information Technology, : Frederick MD | 7.718       | 0.749                                   |            | 0.666   |            | 0.605                    |            | -           |            | 0.605          | 0.000            | 9.738      | -                        |
| <b>Subtotal</b>  |                        |   | 36.548      | 3.488                                   |            | 0.933   |            | 0.917                    |            | -           |            | 0.917          | Continuing       | Continuing | N/A                      |
| Product Development (\$ in Millions)   |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base             |            | FY 2022 OCO |            | FY 2022 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                         | 33.686      | 0.849                                   |            | -       |            | -                        |            | -           |            | -              | Continuing       | Continuing | Continuing               |
| Rapid Diagnostic and Detection Devices   | C/Various              | Inbios, Inc : Seattle WA                                | 1.997       | 6.434                                   |            | 2.748   |            | -                        |            | -           |            | -              | 0.000            | 11.179     | -                        |
| Rapid Diagnostic and Detection Devices (MPDS)  | Various                | Cepheid : CA  | -           | -                                       |            | -       |            | 2.092                    |            | -           |            | 2.092          | 0.000            | 2.092      | -                        |
| Treatment for Resistant Infections - Antifungal Drug   | Various                | TBD : TBD   | -           | -                                       |            | 1.946   |            | -                        |            | -           |            | -              | 0.000            | 1.946      | -                        |
| Next Generation Malaria Drug (D5P)   | Various                | TBD : TBD   | -           | -                                       |            | 2.627   |            | -                        |            | -           |            | -              | 0.000            | 2.627      | -                        |
| Staphylococcus aureus Vaccine  | Various                | TBD : TBD   | -           | -                                       |            | 1.772   |            | 0.968                    |            | -           |            | 0.968          | 0.000            | 2.740      | -                        |
| Treatment for Drug Resistant Battlefield Wound Infections (Formerly Treatment for Resistant Wound In | Various                | TBD : TBD   | -           | -                                       |            | -       |            | 2.500                    |            | -           |            | 2.500          | 0.000            | 2.500      | -                        |
| <b>Subtotal</b>  |                        |   | 35.683      | 7.283                                   |            | 9.093   |            | 5.560                    |            | -           |            | 5.560          | Continuing       | Continuing | N/A                      |



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**Exhibit R-4, RDT&E Schedule Profile: PB 2022 Army** **Date:** May 2021

|  |  |   |
|--|--|---|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>808 / <i>DoD Drug &amp; Vacc Ad</i> |
|--|--|---|

| Event Name   | FY 2020   |   |   |   | FY 2021 |   |   |   | FY 2022 |   |   |   | FY 2023 |   |   |   | FY 2024 |   |   |   | FY 2025 |   |   |   | FY 2026 |   |   |   |
|--|-----------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
|  | 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 |
| Treatment for Resistant Wound Infections Antifungal Drug Phase 1 | FY16-FY23 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |
| Rapid Human Diagnostic Devices                                   | FY17-FY25 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |
| Staphylococcus aureus Vaccine                                    | FY17-FY25 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |

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**Exhibit R-4A, RDT&E Schedule Details:** PB 2022 Army **Date:** May 2021

|  |  |   |
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| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>808 / <i>DoD Drug &amp; Vacc Ad</i> |
|--|--|---|

Schedule Details

| Events  | Start   |      | End     |      |
|---|---------|------|---------|------|
|   | Quarter | Year | Quarter | Year |
| Treatment for Resistant Wound Infections Antifungal Drug Phase 2 safety trial | 1       | 2017 | 4       | 2023 |
| Rapid Human Diagnostic Devices  | 4       | 2017 | 4       | 2025 |
| Staphylococcus aureus Vaccine   | 4       | 2022 | 4       | 2024 |

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|  |                    |                |                |                     |  |                      |                |                |   |                       |                         |                   |
|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|---|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |                    |                |                |                     |  |                      |                |                |   | <b>Date:</b> May 2021 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> |                      |                |                | <b>Project (Number/Name)</b><br>811 / <i>Mil HIV Vac&amp;Drug Dev</i> |                       |                         |                   |
| <b>COST (\$ in Millions)</b>                                       | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>   | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b>  | <b>FY 2026</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| 811: <i>Mil HIV Vac&amp;Drug Dev</i>                               | -                  | 5.236          | 4.912          | -                   | -  | -                    | -              | -              | -   | -                     | -                       | -                 |
| Quantity of RDT&E Articles   | -                  | -              | -              | -                   | -  | -                    | -              | -              | -   | -                     |                         |                   |

**Note**

For Fiscal Year (FY) 2022 the program funding has transitioned to Program Element (PE) 0604807A Project 849.

**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. Products from this Project will transition to PE 0604807A/Project 812.

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)**

|  | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|--|----------------|----------------|----------------|
| <b>Title:</b> Military HIV Vaccine & Drug Development  | 5.236          | 4.912          | -              |
| <b>Description:</b> 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. |                |                |                |
| <b>FY 2021 Plans:</b><br>Global Vaccine Candidate: Will continue to support clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.  |                |                |                |
| <b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br>For FY 2022 the program funding has transitioned to PE 0604807A Project 849.   |                |                |                |
| <b>Accomplishments/Planned Programs Subtotals</b>  | 5.236          | 4.912          | -              |

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

N/A

**Remarks**

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**Exhibit R-2A, RDT&E Project Justification:** PB 2022 Army **Date:** May 2021

|  |  |   |
|--|--|---|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>811 / <i>Mil HIV Vac&amp;Drug Dev</i> |
|--|--|---|

**D. Acquisition Strategy**

Test and evaluate commercially developed drug/vaccine candidates in government-managed trials.

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army** **Date:** May 2021

|  |   |  |
|--|---|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>811 / Mil HIV Vac&Drug Dev |
|--|---|--|

| <b>Management Services (\$ in Millions)</b>          |                                   |   |                    | <b>FY 2020</b> |                   | <b>FY 2021</b> |                   | <b>FY 2022 Base</b> |                   | <b>FY 2022 OCO</b> |                   | <b>FY 2022 Total</b> | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</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>          |                         |                   |                                 |
| Medical Product Development Management Services Cost | TBD                               | Not Applicable : Not Applicable           | 4.132              | 0.183          |                   | -              |                   | -                   |                   | -                  |                   | -                    | Continuing              | Continuing        | Continuing                      |
| <b>Subtotal</b>                                      |                                   |   | 4.132              | 0.183          |                   | -              |                   | -                   |                   | -                  |                   | -                    | Continuing              | Continuing        | N/A                             |

**Remarks**  
Not Applicable

| <b>Product Development (\$ in Millions)</b> |                                   |   |                    | <b>FY 2020</b> |                   | <b>FY 2021</b> |                   | <b>FY 2022 Base</b> |                   | <b>FY 2022 OCO</b> |                   | <b>FY 2022 Total</b> | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</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>          |                         |                   |                                 |
| Medical Product Development Cost            | TBD                               | Not applicable : Not applicable           | 5.078              | -              |                   | -              |                   | -                   |                   | -                  |                   | -                    | Continuing              | Continuing        | Continuing                      |
| <b>Subtotal</b>                             |                                   |   | 5.078              | -              |                   | -              |                   | -                   |                   | -                  |                   | -                    | Continuing              | Continuing        | N/A                             |

| <b>Support (\$ in Millions)</b>          |                                   |   |                    | <b>FY 2020</b> |                   | <b>FY 2021</b> |                   | <b>FY 2022 Base</b> |                   | <b>FY 2022 OCO</b> |                   | <b>FY 2022 Total</b> | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</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>          |                         |                   |                                 |
| Medical Product Development Support Cost | TBD                               | TBD : TBD                                 | 4.541              | -              |                   | -              |                   | -                   |                   | -                  |                   | -                    | 0.000                   | 4.541             | -                               |
| <b>Subtotal</b>                          |                                   |   | 4.541              | -              |                   | -              |                   | -                   |                   | -                  |                   | -                    | 0.000                   | 4.541             | N/A                             |

**Remarks**  
Not Applicable

| <b>Test and Evaluation (\$ in Millions)</b> |                                   |   |                    | <b>FY 2020</b> |                   | <b>FY 2021</b> |                   | <b>FY 2022 Base</b> |                   | <b>FY 2022 OCO</b> |                   | <b>FY 2022 Total</b> | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</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>          |                         |                   |                                 |
| Medical Product Development T&E Cost        | TBD                               | Not applicable : Not Applicable           | 28.204             | 5.053          |                   | 3.748          |                   | -                   |                   | -                  |                   | -                    | 0.000                   | 37.005            | -                               |

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army** **Date:** May 2021

|  |   |  |
|--|---|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>811 / Mil HIV Vac&Drug Dev |
|--|---|--|

| Test and Evaluation (\$ in Millions) |                        |                                |             | FY 2020 |            | FY 2021 |            | FY 2022 Base |            | FY 2022 OCO |            | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--------------------------------------|------------------------|--------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item                   | Contract Method & Type | Performing Activity & Location | Prior Years | Cost    | Award Date | Cost    | Award Date | Cost         | Award Date | Cost        | Award Date | Cost          |                  |            |                          |
| Medical Product Development T&E Cost | C/CPFF                 | PPD : Wilmington, NC           | -           | -       |            | 1.164   |            | -            |            | -           |            | -             | 0.000            | 1.164      | -                        |
| <b>Subtotal</b>                      |                        |                                | 28.204      | 5.053   |            | 4.912   |            | -            |            | -           |            | -             | 0.000            | 38.169     | N/A                      |

**Remarks**  
Not Applicable

|                            | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|----------------------------|-------------|---------|---------|--------------|-------------|---------------|------------------|------------|--------------------------|
| <b>Project Cost Totals</b> | 41.955      | 5.236   | 4.912   | -            | -           | -             | Continuing       | Continuing | N/A                      |

**Remarks**

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**Exhibit R-4, RDT&E Schedule Profile: PB 2022 Army** **Date:** May 2021

|  |  |   |
|--|--|---|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>811 / <i>Mil HIV Vac&amp;Drug Dev</i> |
|--|--|---|

| Event Name   | FY 2020   |   |   |   | FY 2021 |   |   |   | FY 2022 |   |   |   | FY 2023 |   |   |   | FY 2024 |   |   |   | FY 2025 |   |   |   | FY 2026 |   |   |   |
|--|-----------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
|  | 1         | 2 | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4 | 1       | 2 | 3 | 4 |
| Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial         | FY18-FY21 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |
| Global HIV (Ad26/Ad26+gp140) Phase 3 Efficacy Clinical Trial | FY20-FY24 |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |

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**Exhibit R-4A, RDT&E Schedule Details:** PB 2022 Army **Date:** May 2021

|  |  |   |
|--|--|---|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>811 / <i>Mil HIV Vac&amp;Drug Dev</i> |
|--|--|---|

Schedule Details

| Events   | Start   |      | End     |      |
|--|---------|------|---------|------|
|  | Quarter | Year | Quarter | Year |
| Global HIV (Ad26/Ad26+gp140) Phase 2B Clinical Trial         | 1       | 2019 | 1       | 2022 |
| Global HIV (Ad26/Ad26+gp140) Phase 3 Efficacy Clinical Trial | 4       | 2020 | 1       | 2025 |

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|--|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|--|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |                    |                |                |                     |   |                      |                |                |  | <b>Date:</b> May 2021 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev |                      |                |                | <b>Project (Number/Name)</b><br>836 / Field Medical Systems Advanced Development |                       |                         |                   |
| <b>COST (\$ in Millions)</b>                                       | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>  | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b>   | <b>FY 2026</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| 836: Field Medical Systems Advanced Development                    | -                  | 13.587         | 17.335         | 15.594              | -   | 15.594               | -              | -              | -  | -                     | -                       | -                 |
| 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. Products from this project will transition to PE 0604807A/Project 832.

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

|  | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|--|----------------|----------------|----------------|
| <p><b>Title:</b> Field Medical Systems Advanced Development - Program Management (PM) Warfighter Expeditionary Medicine and Treatment</p> <p><b>Description:</b> Funding is provided for the development of the following medical devices in support of enhanced combat casualty care.</p> <p><b>FY 2021 Plans:</b><br/>                     Temporary Corneal Repair: Will conduct initial clinical trials in humans to assess safety.<br/>                     Extracorporeal Life Support - Lung/Renal: Continue pre-clinical and/or clinical studies for the lung and renal components required by the Food and Drug Administration.<br/>                     Non-invasive neuro assessment device (NINAD): Moved to WBH due to PMO Reorganization.<br/>                     Extremity Injury Repair ? Vascular: Will continue ongoing clinical trials for military relevant applications. Will continue ongoing manufacturing contract.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>                     Program efforts realigned to Field Medical Systems Advanced in FY22.</p> | 3.178          | 10.782         | -              |
| <p><b>Title:</b> Field Medical Systems Advanced Development - PM Warfighter Health, Performance and Evacuation</p> <p><b>Description:</b> Funding is provided for the following efforts in the development of products that support the medical mission in combat casualty care and health care operations.</p> <p><b>FY 2021 Plans:</b></p>   | 5.259          | 1.053          | -              |

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|---|--|---|----------------|----------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army  |  | <b>Date:</b> May 2021   |                |                |
| <b>Appropriation/Budget Activity</b><br>2040 / 4  | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>836 / <i>Field Medical Systems Advanced Development</i> |                |                |
| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>   |  | <b>FY 2020</b>  | <b>FY 2021</b> | <b>FY 2022</b> |
| <p>Nett Warrior Enhanced Physiological Sensors (Wearable): Consolidated with, and funded under, Concussion Dosimetry for mTBI Assessment below.</p> <p>Concussion Dosimetry for mTBI Assessment: Prepare sensor and algorithms for validation, verification and operational evaluation or transition to PE 654807 (0604807A)/832.</p> <p>Transport Telemedicine Systems (TTS) (Formerly named Operational Virtual Health): Initiate and complete MEDHUB Increment 1 airworthiness, cyber security and other certifications. Continue development of MEDHUB Increment 2 Drug Safety and Tracking system.</p> <p>Next Generation Uniform Repellent/Impregnation: Project was completed and transitioned to PEO Soldier in FY 2020.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>Program efforts realigned to Field Medical Systems Advanced in FY22.</p>   |  |   |                |                |
| <p><b>Title:</b> Field Medical Systems Advanced Development - PM Tissue Injury and Regenerative Medicine</p> <p><b>Description:</b> Funding for engineering and manufacturing development of tissue injury and regenerative medicine health products for enhanced medical capability and readiness</p>  |  | 5.150   | -              | -              |
| <p><b>Title:</b> Field Medical Systems Advanced Development - Medical Readiness</p> <p><b>Description:</b> Funding is provided for engineering and manufacturing development of medical products for diagnostic devices and testing of medical devices for use in the field.</p> <p><b>FY 2022 Plans:</b><br/>Non-invasive Neuro Assessment Devices (NINAD): Will complete an analysis of alternatives report. Will award R&amp;D contract for development of NINAD capability. Will initiate bench performance testing to demonstrate adequate performance in the laboratory. Will begin protocol development and infrastructure preparation for field evaluation / clinical trial(s) to demonstrate effectiveness in a defined Traumatic Brain Injury population to enable U.S. FDA approval.<br/>XXXXXX</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>Increase due to restructuring of R-Forms input</p> |  | -   | -              | 4.203          |
| <p><b>Title:</b> Field Medical Systems Advanced Development - Battlefield Care and Return to Fight</p> <p><b>Description:</b> Funding is provided for the development of the medical devices in support of enhanced combat casualty care.</p>   |  | -   | -              | 6.014          |

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |   | <b>Date:</b> May 2021  |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>836 / Field Medical Systems Advanced Development |

| <b>B. Accomplishments/Planned Programs (\$ in Millions)</b>  | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|--|----------------|----------------|----------------|
| <p><b>FY 2022 Plans:</b><br/>                     Temporary Corneal Repair: Will continue initial clinical trials and conduct activities to support FDA clearance of TCR product. Will perform developmental and military-relevant testing of product candidates.<br/>                     Extracorporeal Life Support - Lung/Renal: Closing out current contract activities in FY21. Candidate returned to technology base for refinement to meet MDO CONOPS.<br/>                     Burn Treatment Skin Repair- Burn Conversion Prevention: Will award prototyping agreements for products needed to treat severe burns in prolonged care scenarios<br/>                     Freeze Dried Platelets: Conduct market research, develop CRADA's with industry partners and initiate acquisition documentation for a candidate from industry and begin planning for a Phase 2 safety and efficacy trial of the candidate.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>                     Increase due to restructuring of R-Forms input</p> |                |                |                |
| <p><b>Title:</b> Field Medical Systems Advanced Development - Field Hospital and Evacuation</p> <p><b>Description:</b> Funding is provided for the development of the medical devices in support of support the medical mission in health care operations and evacuation.</p> <p><b>FY 2022 Plans:</b><br/>                     Transport Telemedicine Systems (TTS): Will start TTS MEDHUB (Medical Hands-Free Unified Broadcast) Increment 2, which will focus on FDA approval and development (ruggedization for a high vibration environment, etc) of peripheral medical devices that will communicate with MEDHUB. The peripheral medical devices include Drug Safety and Tracking System, Intravenous Pressure Infuser and Blood Pressure Monitor.</p> <p><b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br/>                     Increase due to restructuring of R-Forms input</p>   | -              | -              | 5.377          |
| <b>Accomplishments/Planned Programs Subtotals</b>  | 13.587         | 11.835         | 15.594         |

|   | <b>FY 2020</b> | <b>FY 2021</b> |
|---|----------------|----------------|
| <b>Congressional Add:</b> Program increase - composite shelter  | -              | 5.500          |
| <b>FY 2021 Plans:</b> Develop and test advanced fully composite shelters to improve Hospital Center operations. |                |                |
| <b>Congressional Adds Subtotals</b>   | -              | 5.500          |

|   |
|---|
| <b>C. Other Program Funding Summary (\$ in Millions)</b><br>N/A |
|---|

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |  | <b>Date:</b> May 2021   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>836 / <i>Field Medical Systems Advanced Development</i> |

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

**Remarks**

**D. Acquisition Strategy**

Develop in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army |                        |  |             |   |            |         |            |  |            |             |            | Date: May 2021 |                  |            |                          |
|--|------------------------|--|-------------|---|------------|---------|------------|--|------------|-------------|------------|----------------|------------------|------------|--------------------------|
| Appropriation/Budget Activity                          |                        |  |             | R-1 Program Element (Number/Name)       |            |         |            | Project (Number/Name)                            |            |             |            |                |                  |            |                          |
| 2040 / 4   |                        |  |             | PE 0603807A / Medical Systems - Adv Dev |            |         |            | 836 / Field Medical Systems Advanced Development |            |             |            |                |                  |            |                          |
| Management Services (\$ in Millions)                   |                        |  |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base                                     |            | FY 2022 OCO |            | FY 2022 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  | 47.729      | 0.581                                   |            | 0.604   |            | 1.582  |            | -           |            | 1.582          | Continuing       | Continuing | Continuing               |
| Medical Product Development Management Services Cost   | C/IDIQ                 | Not applicable : Not applicable  | 2.295       | -                                       |            | -       |            | 0.150  |            | -           |            | 0.150          | 0.000            | 2.445      | -                        |
| <b>Subtotal</b>  |                        |  | 50.024      | 0.581                                   |            | 0.604   |            | 1.732  |            | -           |            | 1.732          | Continuing       | Continuing | N/A                      |
| Product Development (\$ in Millions)                   |                        |  |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base                                     |            | FY 2022 OCO |            | FY 2022 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 |
| Temporary Corneal Repair                               | C/Various              | Ashvattha Therapeutics, LLC , University of Southern California, Institute of Surgical Research : Redwood City, CA, Los Angeles, CA, San Antonio, TX | 6.835       | 2.424                                   |            | 4.462   |            | 2.178  |            | -           |            | 2.178          | 0.000            | 15.899     | -                        |
| Extracorporeal Life Support (ECLS)                     | Various                | Medical Technology Enterprise Consortium : Summerville SC  | -           | 0.558                                   |            | 3.150   |            | -  |            | -           |            | -              | 0.000            | 3.708      | -                        |
| Non-invasive neuro assessment device (NINAD)           | C/Various              | TBD : TBD  | 0.800       | -                                       |            | -       |            | 1.471  |            | -           |            | 1.471          | 0.000            | 2.271      | -                        |
| Transport Telemedicine Systems (TTS) - MEDHUB Platform | TBD                    | TBD : TBD  | 0.350       | 1.936                                   |            | -       |            | 2.899  |            | -           |            | 2.899          | Continuing       | Continuing | Continuing               |
| Extremity Injury Repair - Vascular                     | TBD                    | SS/CPFF : HumaCyte: Morrisville, NC  | 1.778       | 4.832                                   |            | 2.531   |            | -  |            | -           |            | -              | Continuing       | Continuing | Continuing               |

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army** **Date:** May 2021

|  |   |  |
|--|---|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>836 / Field Medical Systems Advanced Development |
|--|---|--|

| <b>Product Development (\$ in Millions)</b>            |                        |                                |             | FY 2020 |            | FY 2021 |            | FY 2022 Base |            | FY 2022 OCO |            | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|--------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item                                     | Contract Method & Type | Performing Activity & Location | Prior Years | Cost    | Award Date | Cost    | Award Date | Cost         | Award Date | Cost        | Award Date | Cost          |                  |            |                          |
| Nett Warrior Enhanced Physiological Sensors (Wearable) | TBD                    | Various : Various              | -           | 0.820   |            | -       |            | -            |            | -           |            | -             | Continuing       | Continuing | Continuing               |
| Burn Treatment Skin Repair                             | TBD                    | TBD : TBD                      | -           | -       |            | -       |            | 3.265        |            | -           |            | 3.265         | 0.000            | 3.265      | -                        |
| Freeze Dried Platelets                                 | TBD                    | TBD : TBD                      | -           | -       |            | -       |            | 0.316        |            | -           |            | 0.316         | 0.000            | 0.316      | -                        |
| <b>Subtotal</b>  |                        |                                | 9.763       | 10.570  |            | 10.143  |            | 10.129       |            | -           |            | 10.129        | Continuing       | Continuing | N/A                      |

| <b>Support (\$ in Millions)</b>          |                        |                                 |             | FY 2020 |            | FY 2021 |            | FY 2022 Base |            | FY 2022 OCO |            | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|---------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item                       | Contract Method & Type | Performing Activity & Location  | Prior Years | Cost    | Award Date | Cost    | Award Date | Cost         | Award Date | Cost        | Award Date | Cost          |                  |            |                          |
| Medical Product Development Support Cost | Various                | Not Applicable : Not applicable | 49.441      | 1.758   |            | 1.088   |            | 1.842        |            | -           |            | 1.842         | Continuing       | Continuing | Continuing               |
| Program increase - composite shelter     | TBD                    | TBD : TBD                       | -           | -       |            | 5.500   |            | -            |            | -           |            | -             | 0.000            | 5.500      | -                        |
| <b>Subtotal</b>                          |                        |                                 | 49.441      | 1.758   |            | 6.588   |            | 1.842        |            | -           |            | 1.842         | Continuing       | Continuing | N/A                      |

**Remarks**  
No product/contract costs greater than \$1M individually.

| <b>Test and Evaluation (\$ in Millions)</b>  |                        |                                 |             | FY 2020 |            | FY 2021 |            | FY 2022 Base |            | FY 2022 OCO |            | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--|------------------------|---------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item                           | Contract Method & Type | Performing Activity & Location  | Prior Years | Cost    | Award Date | Cost    | Award Date | Cost         | Award Date | Cost        | Award Date | Cost          |                  |            |                          |
| Medical Product Development T&E Cost         | TBD                    | Not applicable : Not applicable | 39.276      | 0.678   |            | -       |            | -            |            | -           |            | -             | Continuing       | Continuing | Continuing               |
| Noninvasive Neuro-Assessment Devices (NINAD) | TBD                    | TBD : TBD                       | -           | -       |            | -       |            | 1.891        |            | -           |            | 1.891         | 0.000            | 1.891      | -                        |
| <b>Subtotal</b>                              |                        |                                 | 39.276      | 0.678   |            | -       |            | 1.891        |            | -           |            | 1.891         | Continuing       | Continuing | N/A                      |

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**Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army** **Date:** May 2021

|  |   |  |
|--|---|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev | <b>Project (Number/Name)</b><br>836 / Field Medical Systems Advanced Development |
|--|---|--|

| Test and Evaluation (\$ in Millions) |                        |                                |             | FY 2020 |            | FY 2021 |            | FY 2022 Base |            | FY 2022 OCO |            | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|--------------------------------------|------------------------|--------------------------------|-------------|---------|------------|---------|------------|--------------|------------|-------------|------------|---------------|------------------|------------|--------------------------|
| Cost Category Item                   | Contract Method & Type | Performing Activity & Location | Prior Years | Cost    | Award Date | Cost    | Award Date | Cost         | Award Date | Cost        | Award Date | Cost          |                  |            |                          |

**Remarks**  
No product/contract costs greater than \$1M individually.

|                            | Prior Years | FY 2020 | FY 2021 | FY 2022 Base | FY 2022 OCO | FY 2022 Total | Cost To Complete | Total Cost | Target Value of Contract |
|----------------------------|-------------|---------|---------|--------------|-------------|---------------|------------------|------------|--------------------------|
| <b>Project Cost Totals</b> | 148.504     | 13.587  | 17.335  | 15.594       | -           | 15.594        | Continuing       | Continuing | N/A                      |

**Remarks**



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|   |  |   |
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| <b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2022 Army |  | <b>Date:</b> May 2021   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4              | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>836 / <i>Field Medical Systems Advanced Development</i> |

Schedule Details

| Events   | Start   |      | End     |      |
|--|---------|------|---------|------|
|  | Quarter | Year | Quarter | Year |
| Temporary Corneal Repair   | 2       | 2016 | 1       | 2024 |
| Temporary Corneal Repair -Prototype Testing                                      | 2       | 2018 | 1       | 2024 |
| Temporary Corneal Repair- Clinical Study   | 2       | 2021 | 4       | 2023 |
| Noninvasive Neuro Assessment Device development (NINAD)                          | 1       | 2019 | 1       | 2025 |
| Transport Telemedicine Systems (TTS)- MEDHUB Platform                            | 3       | 2013 | 1       | 2022 |
| Transport Telemedicine Systems (TTS)- MEDHUB Drug Safety and Tracking            | 1       | 2018 | 3       | 2024 |
| Extremity Injury Repair (Per. Acellular Arterial Graft) - Vascular Pivotal Study | 1       | 2020 | 1       | 2022 |
| Extremity Injury Repair - Vascular- Environmental Testing/Operational Testing    | 1       | 2021 | 1       | 2022 |
| Burn Treatment Skin Repair   | 1       | 2023 | 1       | 2025 |
| Freeze Dried Platelets   | 3       | 2022 | 3       | 2025 |

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|--|--------------------|----------------|----------------|---------------------|--|----------------------|----------------|----------------|--|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |                    |                |                |                     |  |                      |                |                |  | <b>Date:</b> May 2021 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> |                      |                |                | <b>Project (Number/Name)</b><br>FF4 / <i>Counterdrug, DDR, Sys Development &amp; Demonstration</i> |                       |                         |                   |
| <b>COST (\$ in Millions)</b>                                       | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>   | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b>   | <b>FY 2026</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| <i>FF4: Counterdrug, DDR, Sys Development &amp; Demonstration</i>  | -                  | 0.500          | -              | -                   | -  | -                    | -              | -              | -  | -                     | -                       | -                 |
| 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.

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

|   | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|---|----------------|----------------|----------------|
| <b>Title:</b> FF4                                 | 0.500          | -              | -              |
| <b>Accomplishments/Planned Programs Subtotals</b> | 0.500          | -              | -              |

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

N/A

**Remarks**

**D. Acquisition Strategy**

N/A





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| <b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2022 Army |  | <b>Date:</b> May 2021  |
| <b>Appropriation/Budget Activity</b><br>2040 / 4              | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>FF4 / <i>Counterdrug, DDR, Sys Development &amp; 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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|--|--------------------|----------------|----------------|---------------------|---|----------------------|----------------|----------------|---|-----------------------|-------------------------|-------------------|
| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army |                    |                |                |                     |   |                      |                |                |   | <b>Date:</b> May 2021 |                         |                   |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                   |                    |                |                |                     | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / Medical Systems - Adv Dev |                      |                |                | <b>Project (Number/Name)</b><br>VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev |                       |                         |                   |
| <b>COST (\$ in Millions)</b>                                       | <b>Prior Years</b> | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022 Base</b> | <b>FY 2022 OCO</b>  | <b>FY 2022 Total</b> | <b>FY 2023</b> | <b>FY 2024</b> | <b>FY 2025</b>  | <b>FY 2026</b>        | <b>Cost To Complete</b> | <b>Total Cost</b> |
| <i>VS7: MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i>      | -                  | 6.081          | 0.291          | -                   | -   | -                    | -              | -              | -   | -                     | -                       | -                 |
| Quantity of RDT&E Articles   | -                  | -              | -              | -                   | -   | -                    | -              | -              | -   | -                     |                         |                   |

**Note**

Other Army requirements will take precedence and this effort will terminate.

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

This Project is funded to achieve the required operational capability and common capability across the MEDEVAC fleet. The MEDEVAC MEP program modernizes and retrofits MEDEVAC legacy helicopters to achieve the medical capability provided by a limited number of mission specific MEDEVAC helicopters, to include Blackhawk and Future Vertical Lift. The Medevac Mission Equipment on the Army MEDEVAC helicopters is critical to maintaining high US troop survival rates during current and future conflicts by evacuating wounded troops quickly while providing good care enroute. To better meet operational needs, in 2009 the Vice Chief of Staff of the Army (VCSA) approved the force design update increasing the number of air frames for MEDEVAC companies. In 2010, the Army Medical Department (US Army) accepted life-cycle management of the MEDEVAC MEP from PEO Aviation. Ongoing research and design efforts are required to prepare and optimize the MEDEVAC fleet with mission equipment. All products from this Project will transition to PE 0604807A/Project VS8.

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

|   | <b>FY 2020</b> | <b>FY 2021</b> | <b>FY 2022</b> |
|---|----------------|----------------|----------------|
| <b>Title:</b> Medical Evacuation Development  | 0.281          | 0.291          | -              |
| <b>Description:</b> This effort involves 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. |                |                |                |
| <b>FY 2021 Plans:</b><br>Future Vertical Lift (FVL) Aeromedical Evacuation Patient Handling System Design: Continue to develop and design patient handling system for Future Vertical Lift so medics can effectively treat patients during MEDEVAC Missions.  |                |                |                |
| <b>FY 2021 to FY 2022 Increase/Decrease Statement:</b><br>Other Army requirements will take precedence and this effort will terminate   |                |                |                |
| <b>Accomplishments/Planned Programs Subtotals</b>   | 0.281          | 0.291          | -              |

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| <b>Exhibit R-2A, RDT&amp;E Project Justification:</b> PB 2022 Army | <b>Date:</b> May 2021 |
|--|-----------------------|

|  |  |  |
|--|--|--|
| <b>Appropriation/Budget Activity</b><br>2040 / 4 | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> |
|--|--|--|

|  | FY 2020 | FY 2021 |
|--|---------|---------|
| <b>Congressional Add:</b> Transport Telemedicine       | 5.800   | -       |
| <b>FY 2020 Accomplishments:</b> Transport Telemedicine |         |         |
| <b>Congressional Adds Subtotals</b>                    | 5.800   | -       |

**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.

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| Exhibit R-3, RDT&E Project Cost Analysis: PB 2022 Army |                        |   |             |   |            |         |            |   |            |             |            | Date: May 2021 |                  |            |                          |  |
|--|------------------------|---|-------------|---|------------|---------|------------|---|------------|-------------|------------|----------------|------------------|------------|--------------------------|--|
| Appropriation/Budget Activity                          |                        |   |             | R-1 Program Element (Number/Name)       |            |         |            | Project (Number/Name)                                   |            |             |            |                |                  |            |                          |  |
| 2040 / 4   |                        |   |             | PE 0603807A / Medical Systems - Adv Dev |            |         |            | VS7 / MEDEVAC Mission Equipment Package (MEP) - Adv Dev |            |             |            |                |                  |            |                          |  |
| <b>Management Services (\$ in Millions)</b>            |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base  |            | FY 2022 OCO |            | FY 2022 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 Services Cost              | Various                | APM MEDEVAC<br>PEO Aviation :<br>Huntsville, AL | 0.611       | 3.054                                   |            | 0.291   |            | -   |            | -           |            | -              | 0.000            | 3.956      | -                        |  |
| <b>Subtotal</b>  |                        |   | 0.611       | 3.054                                   |            | 0.291   |            | -   |            | -           |            | -              | 0.000            | 3.956      | N/A                      |  |
| <b>Product Development (\$ in Millions)</b>            |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base  |            | FY 2022 OCO |            | FY 2022 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<br>PEO Aviation :<br>Huntsville AL  | 1.624       | 3.027                                   |            | -       |            | -   |            | -           |            | -              | 0.000            | 4.651      | -                        |  |
| <b>Subtotal</b>  |                        |   | 1.624       | 3.027                                   |            | -       |            | -   |            | -           |            | -              | 0.000            | 4.651      | N/A                      |  |
| <b>Support (\$ in Millions)</b>                        |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base  |            | FY 2022 OCO |            | FY 2022 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<br>PEO Aviation :<br>Huntsville, AL | 0.911       | -                                       |            | -       |            | -   |            | -           |            | -              | 0.000            | 0.911      | -                        |  |
| <b>Subtotal</b>  |                        |   | 0.911       | -                                       |            | -       |            | -   |            | -           |            | -              | 0.000            | 0.911      | N/A                      |  |
| <b>Test and Evaluation (\$ in Millions)</b>            |                        |   |             | FY 2020                                 |            | FY 2021 |            | FY 2022 Base  |            | FY 2022 OCO |            | FY 2022 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<br>PEO Aviation :<br>Huntsville, AL | 0.199       | -                                       |            | -       |            | -   |            | -           |            | -              | 0.000            | 0.199      | -                        |  |
| <b>Subtotal</b>  |                        |   | 0.199       | -                                       |            | -       |            | -   |            | -           |            | -              | 0.000            | 0.199      | N/A                      |  |

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|---|--------------------|----------------|--|--|--|---------------------|--|--|--|-----------------------|-------------------------|-------------------|---------------------------------|
| <b>Exhibit R-3, RDT&amp;E Project Cost Analysis: PB 2022 Army</b> |                    |                |  |  |  |                     |  |  |  | <b>Date: May 2021</b> |                         |                   |                                 |
| <b>Appropriation/Budget Activity</b><br>2040 / 4                  |                    |                |  | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> |  |                     |  | <b>Project (Number/Name)</b><br>VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> |  |                       |                         |                   |                                 |
|   | <b>Prior Years</b> | <b>FY 2020</b> |  | <b>FY 2021</b>   |  | <b>FY 2022 Base</b> |  | <b>FY 2022 OCO</b>   |  | <b>FY 2022 Total</b>  | <b>Cost To Complete</b> | <b>Total Cost</b> | <b>Target Value of Contract</b> |
| <b>Project Cost Totals</b>  | 3.345              | 6.081          |  | 0.291  |  | -                   |  | -  |  | -                     | 0.000                   | 9.717             | N/A                             |

**Remarks**

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| <b>Exhibit R-4, RDT&amp;E Schedule Profile: PB 2022 Army</b> |  |  | <b>Date:</b> May 2021 |
| <b>Appropriation/Budget Activity</b><br>2040 / 4             | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> |                       |

| Event Name  | FY 2020                  |   |   |   | FY 2021 |   |   |   | FY 2022 |   |   |   | FY 2023 |   |   |   | FY 2024 |   |   |   | FY 2025 |   |   |   | FY 2026 |   |   |   |
|---|--------------------------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|---------|---|---|---|
|   | 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 |
| Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Sp | Research and development |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |         |   |   |   |

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| <b>Exhibit R-4A, RDT&amp;E Schedule Details:</b> PB 2022 Army |  | <b>Date:</b> May 2021  |
| <b>Appropriation/Budget Activity</b><br>2040 / 4              | <b>R-1 Program Element (Number/Name)</b><br>PE 0603807A / <i>Medical Systems - Adv Dev</i> | <b>Project (Number/Name)</b><br>VS7 / <i>MEDEVAC Mission Equipment Package (MEP) - Adv Dev</i> |

Schedule Details

| Events  | Start   |      | End     |      |
|---|---------|------|---------|------|
|   | Quarter | Year | Quarter | Year |
| Future Vertical Lift (FVL) and UH60 Aeromedical Evac Cabin Space and Technology | 1       | 2017 | 4       | 2021 |