# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R2 Exhibit)

**February 2004**

BUDGET ACTIVITY
**3 - Advanced technology development**

PE NUMBER AND TITLE
**0603002A - MEDICAL ADVANCED TECHNOLOGY**

| | COST (In Thousands) | FY 2003 Actual | FY 2004 Estimate | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|---|---|---|---|---|
| | Total Program Element (PE) Cost | 168093 | 217737 | 38404 | 46905 | 51529 | 59159 | 56767 |
| 800 | TELEMEDICINE TESTBED | 1862 | 1961 | 2023 | 3843 | 4312 | 4413 | 4513 |
| 804 | PROSTATE CANCER RSCH | 1001 | 988 | 0 | 0 | 0 | 0 | 0 |
| 810 | IND BASE ID VACC&DRUG | 8432 | 17935 | 19958 | 20278 | 21760 | 22211 | 22717 |
| 814 | NEUROFIBROMATOSIS | 19054 | 19756 | 0 | 0 | 0 | 0 | 0 |
| 818 | ADVANCED CANCER DETECTION CTR | 4762 | 0 | 0 | 0 | 0 | 0 | 0 |
| 819 | FLD MED PROT/HUM PERF | 535 | 1433 | 1588 | 1626 | 1656 | 1695 | 1733 |
| 840 | COMBAT INJURY MGMT | 5773 | 13412 | 14835 | 21158 | 23801 | 30840 | 27804 |
| 893 | TISSUE REPLACEMENT | 0 | 4247 | 0 | 0 | 0 | 0 | 0 |
| 929 | ARTIFICIAL LUNG TECHNOLOGY | 952 | 988 | 0 | 0 | 0 | 0 | 0 |
| 932 | MINIMALLY INVASIVE SURGERY (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| 941 | DIABETES RESEARCH | 10527 | 4939 | 0 | 0 | 0 | 0 | 0 |
| 945 | BREAST CANCER STAMP | 2218 | 0 | 0 | 0 | 0 | 0 | 0 |
| 954 | DIGITAL X-RAY | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| 955 | ASSISTIVE TECHNOLOGY | 0 | 1976 | 0 | 0 | 0 | 0 | 0 |
| 969 | ALCOHOLISM RESEARCH | 3334 | 4445 | 0 | 0 | 0 | 0 | 0 |
| 973 | RECOMBINANT VACCINE RESEARCH | 1905 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97A | BIOSENSOR RESEARCH | 1668 | 2964 | 0 | 0 | 0 | 0 | 0 |
| 97B | BLOOD SAFETY | 7955 | 4050 | 0 | 0 | 0 | 0 | 0 |
| 97D | CENTER FOR AGING EYE | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| 97E | CENTER FOR PROSTATE DISEASE RESEARCH AT WRAMC | 5430 | 4445 | 0 | 0 | 0 | 0 | 0 |
| 97I | DREAMS | 10479 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97N | LUNG CANCER DETECTION | 0 | 5137 | 0 | 0 | 0 | 0 | 0 |
| 97O | LUNG CANCER RESEARCH | 8574 | 9384 | 0 | 0 | 0 | 0 | 0 |
| 97S | MOLECULAR GENETICS AND MUSCULOSKELETAL RESEARCH | 8098 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97T | NEUROTOXIN EXPOSURE TREATMENT | 20243 | 25682 | 0 | 0 | 0 | 0 | 0 |

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|---|---|---|---|---|---|---|---|---|
| 97V | POLYNITROXILATED HEMOGLOBIN | 952 | 0 | 0 | 0 | 0 | 0 | 0 |
| 97W | SEATREAT CANCER TECHNOLOGY | 0 | 1976 | 0 | 0 | 0 | 0 | 0 |
| 97Y | VIRTUAL RETINAL DISPLAY TECHNOLOGY | 1905 | 0 | 0 | 0 | 0 | 0 | 0 |
| MB1 | ADV DIAGNOSTICS & THERAPEUTIC DIG TECH | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| MB2 | BRAIN, BIOLOGY, AND MACHINE | 2857 | 2964 | 0 | 0 | 0 | 0 | 0 |
| MB3 | CENTER FOR INTEGRATION OF MEDICINE & INNOV TECH | 6670 | 11112 | 0 | 0 | 0 | 0 | 0 |
| MB4 | CENTER FOR UNTETHERED HEALTHCARE | 952 | 1481 | 0 | 0 | 0 | 0 | 0 |
| MB7 | HEMOGLOBIN BASED OXYGEN CARRIER | 4287 | 0 | 0 | 0 | 0 | 0 | 0 |
| MB9 | JOINT US NORWEGIAN TELEMEDICINE | 2667 | 2766 | 0 | 0 | 0 | 0 | 0 |
| MC3 | SACCADIC FATIGUE MEASUREMENT | 952 | 0 | 0 | 0 | 0 | 0 | 0 |
| MC4 | SECURE TELEMEDICINE TECH PROGRAM | 1714 | 0 | 0 | 0 | 0 | 0 | 0 |
| MC9 | MEDICAL SIMULATION TRAINING INITIATIVE | 952 | 988 | 0 | 0 | 0 | 0 | 0 |
| MD1 | EMERGENCY TELEMED RESPONSE & ADV TECH | 1905 | 2964 | 0 | 0 | 0 | 0 | 0 |
| ME1 | CHILDREN'S HOSPICE PROGRAM | 1430 | 988 | 0 | 0 | 0 | 0 | 0 |
| ME2 | CLINICAL INFORMATION SYSTEMS INITIATIVE | 1142 | 0 | 0 | 0 | 0 | 0 | 0 |
| ME3 | INSTITUTE FOR RESEARCH AND EDUCATION | 3999 | 3655 | 0 | 0 | 0 | 0 | 0 |
| ME4 | LASER FUSION ELASTIN | 4048 | 0 | 0 | 0 | 0 | 0 | 0 |
| ME5 | MEDICAL VANGUARD FOR DIABETES MANAGEMENT | 2381 | 0 | 0 | 0 | 0 | 0 | 0 |
| ME6 | MOBILE INTEGRATED DIAGNOSTIC/DATA ANALYSIS SYSTEM | 952 | 1186 | 0 | 0 | 0 | 0 | 0 |
| ME7 | RURAL TELEMEDICINE DEMONSTRATION PROJECT | 952 | 1976 | 0 | 0 | 0 | 0 | 0 |
| ME8 | STABLE HEMOSTAT | 1668 | 2964 | 0 | 0 | 0 | 0 | 0 |
| ME9 | BEHAVIORAL/COMPARATIVE GENOMICS | 2906 | 1976 | 0 | 0 | 0 | 0 | 0 |

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|---|---|---|---|---|---|---|---|---|
| MF1 | 3D IMAGING & GENOMIC ANAL - BREAST CANCER MGT (CA) | 0 | 1680 | 0 | 0 | 0 | 0 | 0 |
| MF2 | ADVANCED PROTEOMICS (CA) | 0 | 1186 | 0 | 0 | 0 | 0 | 0 |
| MF3 | BATTLEFIELD RESPIRATOR AND VENTILATOR (BRAV) (CA) | 0 | 1481 | 0 | 0 | 0 | 0 | 0 |
| MF4 | BIO-MEDICAL ENGINEERING CENTER (CA) | 0 | 1186 | 0 | 0 | 0 | 0 | 0 |
| MF5 | BIOMEDICAL INFORMATION TRANSFER (BIT) (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| MF6 | DENDRITIC NANOTECHNOLOGY RESEARCH (CA) | 0 | 2964 | 0 | 0 | 0 | 0 | 0 |
| MF7 | ELECTRICAL IMPEDANCE SCANNING DEVICE (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| MF8 | EMERGING TECHNOLOGIES CENTER (CA) | 0 | 1481 | 0 | 0 | 0 | 0 | 0 |
| MF9 | GENOMIC MEDICINE AND GENE THERAPY (CA) | 0 | 3358 | 0 | 0 | 0 | 0 | 0 |
| MG1 | GYNECOLOGIC DISEASE PROGRAM (CA) | 0 | 4198 | 0 | 0 | 0 | 0 | 0 |
| MG2 | INTEGRATED INFORMATION SYSTEM (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| MG3 | MEDICAL TRAINING TECH ENHANCEMENT INITIATIVE (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |
| MG5 | NATIONAL FUNCTIONAL GENOMICS CENTER (CA) | 0 | 4939 | 0 | 0 | 0 | 0 | 0 |
| MG6 | NOVEL SAFE EFFECT VACCINES FOR BIODEFENSE/CANCER | 0 | 6717 | 0 | 0 | 0 | 0 | 0 |
| MG7 | ON-LINE MEDICAL TRAINING (CA) | 0 | 1729 | 0 | 0 | 0 | 0 | 0 |
| MG8 | OPERATING ROOM OF THE FUTURE (CA) | 0 | 1976 | 0 | 0 | 0 | 0 | 0 |
| MG9 | PENNINGTON BIOMEDICAL CENTER (CA) | 0 | 1778 | 0 | 0 | 0 | 0 | 0 |
| MH1 | PICTURE ARCHIVING AND COMMUNICATIONS SYSTEM (CA) | 0 | 3457 | 0 | 0 | 0 | 0 | 0 |
| MH2 | PROJECT COLLABORATION MATERIAL (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |

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|---|---|---|---|---|---|---|---|---|
| MH3 | PROTEOMICS CENTER (CA) | 0 | 3358 | 0 | 0 | 0 | 0 | 0 |
| MH4 | RAPID BIO-PATHOGEN DETECTION TECHNOLOGY (CA) | 0 | 1481 | 0 | 0 | 0 | 0 | 0 |
| MH5 | REGIONAL ANESTHESIA AND PAIN MGMT INITIATIVE (CA) | 0 | 1186 | 0 | 0 | 0 | 0 | 0 |
| MH6 | RUGGED TEXTILE ELECTRONIC GARMENTS (CA) | 0 | 2964 | 0 | 0 | 0 | 0 | 0 |
| MH7 | STUDY OF HUMAN OPERATOR PERFORMANCE (CA) | 0 | 988 | 0 | 0 | 0 | 0 | 0 |

**A. Mission Description and Budget Item Justification:** This program element (PE) supports focused research for healthy, medically protected soldiers, and funds research consistent with the "Medical" and "Survivability" technology areas of the Future Force and the Food and Drug Administration (FDA). Where feasible, the research exploits opportunities to enhance Current Force capabilities. The primary goal of this program is to provide maximum soldier survivability and sustainability on the battlefield as well as in military operations other than war. This program element funds advanced technology development in three major areas: Core Infectious Diseases Vaccine and Drug Program; Combat Injury Management; and Field Medical Protective devices. Serving as the Lead Agent for Infectious Disease Research, the DoD Core Vaccine and Drug Program provides pharmaceutical grade drugs and vaccines for development that are effective protectants, treatments, and antidotes against military disease threats. This PE also funds new technologies and demonstrations in combat casualty care with the overarching goal of reducing battlefield deaths and stabilizing evacuees in austere medical environments. Other critical areas include Soldier performance under various environmental and physiological stressors as well as the impact of the soldiers' well being from materiel hazards. Overall, this PE funds studies and demonstrations of biomedical products designed to protect, sustain, and enhance soldier performance in such settings. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this PE is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD; U. S. Army Medical Institute of Chemical Defense (USAMRICD), Aberdeen Proving Ground, MD; U. S. Army Medical Institute of Infectious Diseases (UASMRIID), Fort Detrick, MD; U.S. Army Research Institute of Environmental Medicine (USARIEM), Natick, MA; U.S. Army Institute of Surgical Research (USAISR), Fort Sam Houston, TX; and the U.S. Army Aeromedical Research Laboratory (USAARL), Fort Rucker, AL and for infectious disease research, the Naval Medical Research Center (NMRC), Silver Springs, MD. The program element contains no duplication with any effort within the Military Departments.

| B. Program Change Summary | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Previous President's Budget (FY 2004) | 166406 | 35168 | 38686 |
| Current Budget (FY 2005 PB) | 168093 | 217737 | 38404 |
| Total Adjustments | 1687 | 182569 | -282 |
| Congressional program reductions | | -1862 | |
| Congressional rescissions | | | |
| Congressional increases | | 185250 | |
| Reprogrammings | 1687 | -819 | |
| SBIR/STTR Transfer | | | |
| Adjustments to Budget Years | | | -282 |

Change Summary Explanation:FY04 - Fifty-four FY04 Congressional adds totaling $185,250 were added to this PE.

FY04 Congressional adds with no R-2As:
($1,700) 3D Imaging and Genomic Analysis Breast Cancer Management, Project MF1
($1,000) Advanced Diagnostics & Therapeutic Digital Technologies, Project MB1
($1,200) Advanced Proteomics, Project MF2
($2,000) Assistive Technology and Research Center at National Rehabilitation Hospital, Project 955
($1,500) Battlefield Respirator And Ventilator (BRAV), Project MF3
($9,500) Biology, Education, Screening, Chemoprevention and Treatment (BESCT) Lung Cancer Research Program (M.D. Anderson Cancer Center), Project 97O
($1,200) Bio-Medical Engineering Center for Research on Bioterrorism Agents, Project MF4
($1,000) Biomedical Information Transfer (BIT), Project MF5
($4,100) Blood Safety, Project 97B
($3,000) Brain, Biology, And Machine, Project MB2
($11,250) Center for Innovative Minimally Invasive Technology (CIMIT), Project MB3
($4,500) Center for Prostate Disease Research, WRAIR, Project 97E
($1,500) Center for Untethered Healthcare, Project

MB4
($1,000) Military Low Vision Research, Project 97D
($2,000) Comparative Functional Genomics Initiative, Project ME9
($3,000) Dendritic Nanotechnology Research, Project MF6
($1,000) Electrical Impedence Scanning Device, Project MF7
($1,500) Emerging Technologies Center, Project MF8
($3,400) Genomic Medicine Gene Therapy, Project MF9
($4,250) Gynecologic Disease Program, Project MG1
($3,700) Institute For Research And Education, Project ME3
($1,000) Integrated Information System, Project MG2
($1,000) Intravenous Membrane Oxygenator, Project 929
($5,000) Joslin Diabetes Project, Project 941
($2,800) Joint US-Norwegian Telemedicine Program, Project MB9
($1,000) Medical Modeling and Simulation Through Synthetic Digital Genes, Project MC9
($1,000) Medical Training Technology Enhancement Initiative, Project MG3
($1,000) Minimally Invasive Surgery Modeling and Simulation, Project 932
($1,200) Mobile Integrated Diagnostic and Data Analysis System (MIDDAS), Project ME6
($3,000) National Bioterrorism Civilian Medical Response Center (CIMERC), Project MD1
($5,000) National Functional Genomics Center, Project MG5
($20,000) Neurofibromatosis Research Program, Project 814
($4,500) Neurology Gallo Center - Alcoholism Research, Project 969
($26,000) Neurotoxin Exposure Treatment Research Program (NETRP) Parkinson's & Neurological Disorders, Project 97T
($6,800) Novel Safe and Effective Vaccines for Biodefense and Cancer, Project MG6
($1,750) On-Line Medical Training, Project MG7
($2,000) Operating Room of the Future, Project MG8
($1,000) Pediatric Hospice Program at Walter Reed Army Medical Center, Project ME1
($1,800) Pennington Biomedical Center Personnel Readiness and Performance Initiative, Project MG9
($3,500) Picture Archiving and Communications System (PACS), Project MH1
($1,000) Portable Digital X-Ray, Project 954
($1,000) Project Collaboration Material, Project MH2
($1,000) Prostate Cancer Research - Gallo Center, Project 804
($3,400) Proteomics Center, Project MH3
($1,500) Rapid Bio-Pathogen Detection Technology, Project MH4
($1,200) Regional Anesthesia and Pain Management Initiative (RAPMI), Project MH5
($3,000) Rugged Textile Electronic Garments for Combat Casualty Care, Project MH6

($2,000) SEATreat, Project 97W
($3,000) Stable Hemostat, Project ME8
($1,000) Study of Human Operator Performance (C-SHOP), Project MH7
($3,000) Technologies for Metabolic Monitoring, Project 97A
($4,300) Tissue Development on Elastin Biomatrixes, Project 893
($5,200) VCT Lung Scan, Project 97N
($2,000) Idaho Rural Telemedicine Demonstration Project, Project ME7

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

**February 2004**

| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT |
|---|---|---|
| **3 - Advanced technology development** | **0603002A - MEDICAL ADVANCED TECHNOLOGY** | **800** |

| COST (In Thousands) | FY 2003 Actual | FY 2004 Estimate | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|---|---|---|---|
| 800 TELEMEDICINE TESTBED | 1862 | 1961 | 2023 | 3843 | 4312 | 4413 | 4513 |

**A. Mission Description and Budget Item Justification:** This project supports the "Medical" technology area of the Future Force by developing and demonstrating future medical concepts of operations, operational architectures, and operational requirements to support forward echelon telemedicine presence, medical command and control, and collaborative planning tools for mission planning and rehearsal. It funds development, evaluation, and demonstration of prototype advanced technology concepts and materiel for provision of enhanced Force Health Protection. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. The U.S. Army Research Institute of Environmental Medicine, Natick, MA, performs work in this project. This project contains no duplication with any effort within the Military Departments.

| Accomplishments/Planned Program | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Telemedicine ACTD - In FY03, completed an assessment of operational utility and developed a detailed program report for the Office of the Secretary for Defense Advanced Systems and Concepts, U.S. Army Medical Research and Materiel Command (USAMRMC), and the Combatant Commander sponsor. Transitioned products and operational concepts with identified utility and value to applicable programs of record or appropriate combat developers. | 1862 | 0 | 0 |
| Sleep Restriction Impact on Performance and Recovery - In FY04, determine and quantify amount of recovery sleep needed following sleep restriction. In FY05, will determine and quantify the performance-sustaining efficacy of caffeine across 48 hours of sleep deprivation through human trials. | 0 | 1904 | 2023 |
| Small Business Innovative Research/Small Business Technology Transfer Programs | 0 | 57 | 0 |
| Totals | 1862 | 1961 | 2023 |

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

**February 2004**

| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT |
|---|---|---|
| **3 - Advanced technology development** | **0603002A - MEDICAL ADVANCED TECHNOLOGY** | **810** |

| COST (In Thousands) | | FY 2003 Actual | FY 2004 Estimate | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|---|---|---|---|---|
| 810 | IND BASE ID VACC&DRUG | 8432 | 17935 | 19958 | 20278 | 21760 | 22211 | 22717 |

**A. Mission Description and Budget Item Justification:** This project matures and demonstrates medical countermeasures to naturally occurring infectious diseases potentially affecting the Future Force. Infectious diseases pose a significant threat to operational effectiveness and forces deployed outside the United States. Countermeasures will protect the force from infection during sustained operations by preventing hospitalizations and evacuations from the theater of operations. Of major importance to the military are the parasitic disease malaria, the bacterial diseases responsible for diarrhea (i.e., caused by Shigella, enterotoxigenic Escherichia coli (ETEC), and Campylobacter), and viral diseases (i.e., dengue fever and hantaviruses). The program also develops improved materiel for control of insect/arthropod disease vectors and addresses a variety of other threats to deployed and mobilizing forces, including meningitis, viral encephalitis, and hemorrhagic fevers (e.g., hemorrhagic fevers with renal syndrome (HFRS)). Improved diagnostic capabilities are also pursued that enable rapid battlefield identification and management of diseases and allow informed medical and tactical decisions. Program goals include: Preclinical and clinical testing of protein and DNA vaccines; testing new technologies to enhance effectiveness and duration of vaccines; compounding and testing multicomponent vaccines to provide protection against multiple disease strains; producing vaccines and antimalarial drugs under U.S. Food and Drug Administration (FDA) regulated Good Manufacturing Practices and demonstrating their safety and efficacy under FDA Investigational New Drug (IND) applications. Work is managed by the U.S. Army Medical Research and Materiel Command. The Army is the lead service for infectious disease research. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the Walter Reed Army Institute of Research (WRAIR), Silver Spring, MD and its overseas laboratories; U. S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD; and the Naval Medical Research Center (NMRC), Silver Spring, MD and its overseas laboratories. This project contains no duplication with any effort within the Military Departments.

| Accomplishments/Planned Program | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Malaria Vaccines - In FY03, completed clinical testing of DNA-based malaria vaccines. Assessed partially protective Repeated sequence from cirumsporozoite protein; Cell epitope; Hepatitis B surface antigen, Hepatitis B surface antigen (RTS, S) protein vaccine in combination with other falciparum proteins, DNA vaccines and other components for enhanced effectiveness. Continued development of additional vivax candidate vaccines. In FY04, conduct FDA Phase 1 and Phase 2 trials of several candidate malaria vaccine components such as Merozoite Surface Protein – 1 and apical membrane antigen – 1 with the goal of defining the vaccine technology and components for broadly protective malaria vaccine. In FY05, will test and select malaria blood stage vaccine components for integration into lead malaria vaccine candidate; will continue clinical testing of malaria vaccine components. | 2133 | 5330 | 6050 |
| Diarrheal Vaccines - In FY03, successfully completed Phase 1 clinical trial of a Shigella sonnei vaccine, initiated Phase 1 clinical testing of Shigella dysentriae vaccine, and initiated FDA required testing of vaccine components for a multi-agent Invaplex Shigella vaccine. Continued safety and efficacy testing of a candidate vaccine against ETEC diarrhea. Worked toward FDA approval of Phase 1 clinical testing of a protein based Campylobacter vaccine. In FY04, complete Phase 1 clinical trials of multi-agent Shigella vaccine. Conduct Phase 1 clinical studies of Campylobacter vaccines. In FY05, will continue clinical testing of lead Campylobacter vaccine; will initiate Phase 1 clinical trials of additional component of multi-agent Shigella vaccine. | 1064 | 4222 | 3986 |
| Dengue, Meningitis and Hemorrhagic Fever with Renal Syndrome Vaccines - In FY03, started FDA IND applications for clinical trials of dengue DNA and Hemorrhagic Fever and Renal Syndrome (HFRS) vaccines. In FY04, start Phase 1 clinical trials of dengue DNA and inactivated dengue and HFRS vaccines. Start Phase 2 clinical trials of dengue and HFRS vaccines and conduct initial clinical studies of a group B meningococcal vaccine. In FY05, will begin preclinical testing of new molecularly modified dengue virus and tetravalent DNA vaccine candidates, will continue Phase 2 testing of HFRS vaccine, and initiate IND for new group B meningococcal vaccine. | 2843 | 4275 | 4916 |

| **Accomplishments/Planned Program (continued)** | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Antimalarial Drug Candidates - In FY03, completed ongoing preclinical testing of Artesunate antimalarial drug candidate to treat severe malaria and revised testing plan based on FDA guidance; initiated IND application to start clinical testing. Conducted initial preclinical testing in animals of several candidate drugs that prevent malaria and selected best for initial clinical testing. In FY04, complete all FDA-required preclinical toxicity testing of Artesunate and begin Phase 1 clinical testing; move new candidate drugs for prevention of malaria into preclinical testing and down-select best candidate for clinical testing. In FY05, will complete additional clinical testing of Artesunate. Will continue to test drugs to prevent malaria in preclinical trials and select drugs to take to clinical trials. | 2298 | 2048 | 3012 |
| Insect Vector Control and Infectious Disease Diagnostics - In FY03, obtained Army and foreign human use review board approvals for field testing of Dengue Vector Control System (DVCS). In FY04, test DVCS at multiple field sites; identify critical infectious disease diagnostic components for use in a joint services biological agent identification and diagnostic system. In FY05, will continue testing DVCS and component product improvements for FY 06 transition of those DVCS components into advance development; will develop approaches to supplement infectious disease diagnostics not compatible with joint diagnostic system. | 94 | 1647 | 1994 |
| Small Business Innovative Research/Small Business Technology Transfer Programs | 0 | 413 | 0 |
| Totals | 8432 | 17935 | 19958 |

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

**February 2004**

| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT |
|---|---|---|
| **3 - Advanced technology development** | **0603002A - MEDICAL ADVANCED TECHNOLOGY** | **819** |

| COST (In Thousands) | FY 2003 Actual | FY 2004 Estimate | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|---|---|---|---|
| 819 FLD MED PROT/HUM PERF | 535 | 1433 | 1588 | 1626 | 1656 | 1695 | 1733 |

**A. Mission Description and Budget Item Justification:** This project supports "Medical" and "Survivability" technology areas of the Future Force with laboratory validation studies and field demonstrations of biomedical products designed to protect, sustain, and enhance soldier performance in the face of a myriad of environmental and physiological stressors and materiel hazards in training and operational environments. Specific support includes medical development of tools for assessing weapon system user health risks, diagnostic tools, and treatments to rapidly diagnose and treat laser eye injuries on the battlefield, injury prediction tools for assessing soldier survivability and designing effective individual protective equipment, drugs to sustain soldier performance during continuous operations, and tools for assessing health risks to soldiers in operational environments. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the Walter Reed Army Institute of Research, Silver Spring, MD; and U.S. Army Research Institute of Environmental Medicine, Natick, MA.

| **Accomplishments/Planned Program** | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Health Risk Contaminant Detection System/Health and Injury Prevention - In FY03, developed a refined concept demonstration biomonitoring system for detecting chemical contaminants in water for independent evaluation and established a prototype reproductive toxicity test based on preliminary results. Developed health risk assessment software as a method to assess health risks for soldiers exposed to repeated impacts received during tactical operations and accidents in ground vehicles and helicopters. In FY04, demonstrate and validate an Environmental Protection Agency approved nucleic acid-based coliform bacterial detection system to ensure safe drinking water for military preventive medicine teams. In FY05, will conduct testing of a protective drug to decrease or eliminate laser retinal injury in soldiers. | 535 | 1392 | 1588 |
| Small Business Innovative Research/Small Business Technology Transfer Programs | 0 | 41 | 0 |
| Totals | 535 | 1433 | 1588 |

# ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

**February 2004**

| BUDGET ACTIVITY | PE NUMBER AND TITLE | PROJECT |
|---|---|---|
| **3 - Advanced technology development** | **0603002A - MEDICAL ADVANCED TECHNOLOGY** | **840** |

| COST (In Thousands) | | FY 2003 Actual | FY 2004 Estimate | FY 2005 Estimate | FY 2006 Estimate | FY 2007 Estimate | FY 2008 Estimate | FY 2009 Estimate |
|---|---|---|---|---|---|---|---|---|
| 840 | COMBAT INJURY MGMT | 5773 | 13412 | 14835 | 21158 | 23801 | 30840 | 27804 |

**A. Mission Description and Budget Item Justification:** In FY03 through FY07, this project matures and demonstrates new technologies in support of Medical Mission Package (Future Combat Systems (FCS) Increment II) with new candidate intravenous clotting drugs; an assisted critical care support system for far-forward management and transport of casualties; advanced technologies for treating extremity injuries to bone and flesh; freeze-dried plasma that lightens logistical load and provides treatment of hemorrhage; and effective means to enable the combat medic to perform remote triage of battlefield casualties that are widely dispersed on the Future Force battlefield and to thereby maximize field medic resources. In FY03 through FY09, this project matures and demonstrates a handheld device, the "Warrior Medic," that enables the combat medic to quickly link with and assess casualty vital signs and other markers of injury and that provides casualty management guidelines for the medic and an agent that enables field medical personnel to quickly and nonsurgically control internal bleeding. In FY04 through FY09, this project matures and demonstrates new technologies in support of Medical Mission Package (FCS Increment IV) with new and advanced resuscitation fluids and strategies for combat medic administration that improve survival of casualties with severe blood loss (shock) on the battlefield; an automated critical care system for enhanced management, transport, and survival of stabilized casualties within and outside of the battle area; and a handheld system employing acoustic energy to control internal hemorrhage for forward use at the battalion aid station. The project funds prototypes of non-system-specific medical materiel items for far-forward medical management of trauma in combat casualties, including preclinical testing of candidate drugs and biologic compounds and devices/equipment to obtain data necessary for Food and Drug Administration (FDA) approval for human use. Focus areas include testing and demonstrations in drugs and devices to enhance the body's clotting function; strategies and products to optimize casualty resuscitation; novel blood products and medical devices to improve survival and reduce the logistics burden; compact dental technologies and systems for enhanced dental care in the combat zone; and neuroprotective drugs to minimize consequences of head injury. The cited work is consistent with Strategic Planning Guidance, the Army Science and Technology Master Plan, the Army Modernization Plan, and the Defense Technology Area Plan. Work in this project is performed by the U.S. Army Institute of Surgical Research, Fort Sam Houston, TX, U.S. Army Research Institute of Environmental Medicine, Natick, MA, and the Walter Reed Army Institute of Research, Silver Spring, MD.

| Accomplishments/Planned Program | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Pain, Hemorrhage, and Injury Control - In FY03, demonstrated effective eradication of two blood-borne pathogens in a small animal model; conducted animal studies of candidate drugs to enhance blood clotting, and demonstrated the safety of nasally administered ketamine for control of severe pain in a Phase 1 clinical study. In FY04, select a set of sensors that detect ballistic wounding and life signs, integrate with hydration, and sleep status sensors; conduct a Phase 2 clinical trial and initiate a Phase 3 clinical trial to license nasal ketamine for control of pain on the battlefield; study the effectiveness of candidate hemorrhage control agents (gel, foam, liquid) in controlling severe internal bleeding; evaluate wound-protectant device and improved tourniquet device in animals and submit investigational device exemption application to the FDA; conduct proof-of-concept studies of a small antimicrobial wound-cleaning device; conduct proof-of-concept studies of lightweight materials and splints for fracture stabilization; research medical simulation and training requirements; design a methodology to support combat medic training for this highly distributed environment, including treatment of patients exposed to Chemical, Biological and Nuclear weapons. In FY05, will complete algorithms for integration of a set of sensors for detection of ballistic wounding, life signs, and hydration and sleep status into the prototype Future Force Warrior ensemble; will complete Phase 3 clinical trial of nasal ketamine for control of pain on the battlefield; will demonstrate in animals the effectiveness of a handheld device that stops bleeding with sound waves; will study in animals the effectiveness of candidate drugs to enhance blood clotting and restore normal blood clotting; will conduct Phase 1 clinical tests of an improved tourniquet; will conduct tests to select the best wound-cleaning device; and conduct animal tests of lightweight materials for splints. | 3646 | 8396 | 8817 |
| Physiological Status Monitoring - In FY03, demonstrated signal compatibility and non-interference of Land Warrior power system with two candidate life-signs detection systems and the ballistic impact detection system; demonstrated Microimpulse Radar (MIR) vital signs monitor capability to accurately detect and record life-signs data through clothing during physical exertion and reduction of extraneous data caused by motion. In FY04, format MIR monitor into a wearable prototype for continuous soldier monitoring through clothing. In FY05, will transition handheld MIR vital signs monitor to System Development and Demonstration. | 187 | 682 | 1668 |

| **Accomplishments/Planned Program (continued)** | FY 2003 | FY 2004 | FY 2005 |
|---|---|---|---|
| Resuscitation Fluids/Acoustic Hemorrhage Control - In FY03, conducted animal studies of "hypotensive" (keeping blood pressure low) resuscitation comparing commercially available candidate resuscitation fluids in two animal models and demonstrated superiority of one candidate fluid. In FY04, conduct clinical studies to select the best commercially available resuscitation fluid(s). In FY05, will conduct studies in animals of a handheld device for use at the battalion aid station that stops bleeding with sound waves. | 1528 | 3279 | 3534 |
| Dental Disease/Freeze Dried Plasma and Other Combat Injury Related Issues - In FY03, conducted preliminary studies of a system for inactivating infectious agents in both whole blood and red blood cells; and conducted preclinical studies of candidate freeze-dried plasma lots which showed stability in storage for 1 year and showed stable physical and chemical properties after freeze-drying.<br>In FY04, complete development of a new penetrating head injury (PHI) model. Conduct studies of candidate packaging systems for freeze-dried blood products that will enhance delivery and storage of blood products in the field. Initiate development of formulation and application methodology of an anticavity/antiplaque food additive to prevent dental disease.<br>In FY05, will conduct clinical studies of freeze-dried plasma. Will complete development of formulation and application methodology of an anticavity/antiplaque food additive to prevent dental disease. Will conduct neuroprotection drug studies in the PHI model to identify a drug to improve survival and residual brain function in casualties with brain injury. | 412 | 666 | 816 |
| Small Business Innovative Research/Small Business Technology Transfer Programs | 0 | 389 | 0 |
| Totals | 5773 | 13412 | 14835 |