



Medical Systems

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Advanced Planning Briefing to Industry

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Outline



- **Overview**
- **S&T and Warfighter Needs**
- **Technical Challenges**
- **Acquisition Strategy/ Funding/ Schedule**
- **Upcoming Business Opportunities**
- **Contacts**



Science & Technology (S&T) Overview



- **Develop pre-treatments and therapeutics for protection against chemical and biological agents and radiological exposure; develop, assess and validate diagnostic assays for chemical and biological agents**
- **Utilize new biotechnologies to develop broad-spectrum countermeasures against conventional, emerging, and engineered biological threats**
- **Transition FDA-approvable vaccines, drugs and diagnostic assays/devices to advanced development**

Program Overview

- Develop, procure, field, and sustain premier *medical protection and treatment capabilities* against chemical and biological warfare agents.
- Ultimate outcomes are FDA licensed drugs, medical devices and vaccines





S&T Needs



- **Rapid, Broad-Spectrum Chemical Warfare Agent (CWA) and Biological Warfare Agent (BWA) Protection**
- **Multi-agent BWA Prophylaxis**
- **Early Indicators of Exposure/Infection**
- **Effective Countermeasures Against Novel Chemical and Genetically Modified Biological Threats**
- **FDA Approval of Medical Countermeasures and Diagnostics**
- **Radiological Countermeasures**



Warfighter Needs



- Provide the capability to protect service members from the effects of chemical, biological, radiological, and nuclear (CBRN) agents before the appearance of symptoms
 - Medical Identification & Treatment Systems (MITS)
 - Bioscavenger: prevent incapacitation and death from exposure to nerve agents
 - Joint Vaccine Acquisition Program (JVAP) uses the Prime Systems Contract Integrator approach with DynPort Vaccine Company (DVC) to meet DoD biological defense vaccine requirements for vaccines currently in development
 - DVC obtains and maintains FDA licenses



Warfighter Needs (*cont.*)

- Provide the capability to treat service members for the effects of CBRN agents after the appearance of symptoms.
 - Advanced Anticonvulsant System (AAS) will replace Convulsant Antidote Nerve Agent (CANA) system
 - Intramuscular auto-injection of drug (midazolam) for enhanced control of seizures effective against broader spectrum of nerve agents
 - Improved Nerve Agent Treatment System (INATS) active ingredient will replace and provide better protection than current oxime, 2-PAM in current delivery system
 - System approach will also develop broader indications for pretreatment pyridostigmine bromide
 - Medical Radiation Countermeasures will enhance survivability after exposure to ionizing radiation.



Warfighter Needs (*cont.*)



- Provide a reusable, portable, modifiable biological agent identification and diagnostic system capable of simultaneous reliable identification of multiple biological warfare agents and other biological agents of operational significance.
 - Joint Biological Agent Identification and Diagnostic System (JBAIDS) will provide portable diagnostic capability to Warfighter. Evolutionary approach:
 - JBAIDS Block I system capable of identifying 10 Biological Warfare Agents (BWAs)
 - JBAIDS II-A: Reduce to hand held device



S&T Technical Challenges



- **Pre-treatments**

- Understand immune responses to vaccination
- Exploit DNA-based or genetic immunization platforms for rapid vaccine development
- Develop broad-spectrum, multi-agent vaccines to counter emerging threats
- Develop a catalytic nerve agent bioscavenger

- **Therapeutics**

- Develop broad-spectrum therapeutics for BWA
- Develop surrogate efficacy measures and animal models for FDA approval of countermeasures
- Develop effective countermeasures against toxins and chemical agents
- Minimize systemic, neurologic, ocular, and cutaneous injury by CWA



S&T Technical Challenges (cont.)



- **Diagnostics**

- Provide S&T support to advanced developer in the development/assessment of an integrated nucleic acid and immunodiagnostics platform (JBAIDS Block II-A)
- Exploit systems biology tools to develop novel biomarkers as targets for assay development
- Identify presymptomatic diagnostic signatures
- Simplify sample processing
- Assay improvement/expansion

- **Medical Radiological Defense**

- Develop effective pre- and post-exposure radioprotectants
- Reconstitute or facilitate repair of radiogenic damage to hematologic, immunologic, gastrointestinal, and neurological systems



S&T Technical Challenges (*cont.*)



- **Transformational Medical Technologies Initiative (TMTI)**
- **Program goal**
 - **Conduct vigorous medical research to protect the war-fighter from disease and biological warfare agents**
 - **Develop counter-measure products that are regulatory compliant, robust, and highly effective at a reasonable cost**
- **Program to develop broad spectrum countermeasures against two classes of agents**
 - **Hemorrhagic fever viruses**
 - **Intracellular bacterial pathogens**
- **TMTI represents a novel technology and acquisition experiment**



Program Technical Challenges



- **AAS**
 - Ability of the CANA drug-containing chamber to hold midazolam instead of diazepam
 - Stability of midazolam in the drug-containing chamber of the CANA
- **INATS**
 - Active ingredient is new active pharmaceutical ingredient (API) in U.S.
 - Ability to make the candidate oximes IAW cGMP
 - Formulation, stability of the formulation or toxicology problems with candidate oximes
 - Ability of oxime-containing chamber of the Antidote Treatment Nerve Agent Autoinjector (ATNAA) to contain candidate oximes



Program Technical Challenges (cont.)



- **Medical Radiation Countermeasures (FY07)**
 - Address multiple organ system effects
- **Bioscavenger Increment II (FY06)**
 - Select technology (ies) to develop
 - Process development and small scale (cGMP) manufacturing required
- **JBAIDS**
 - FDA approval of device and multiple assays
 - Miniaturization & interoperability



S&T Capability Strategy



- Place Greater Emphasis on Developing Broad-Spectrum Medical Countermeasures
- Exploit Cutting Edge Technologies to Improve Medical Countermeasures
- Accelerate Development Cycle (Rapid Vaccine and Drug Development)
- Leverage Existing Capabilities Found in Other Federal Agencies, Industry, and International Partners
- Sustain Long-term Investment in Developing Candidates for Capability Gaps
- Ensure Knowledge Base to Support Future Technology Development



Program Acquisition Strategy



- Addresses user requirements based on capabilities needed and Joint Staff priorities
- Develops FDA licensed chemical and biological defense (CBD) medical products
- Leverages other government agencies, international partnerships, and industry
- Manages product line within available resources
 - Funds product development efforts to minimize schedules
 - Expands or contracts product line based on available funding

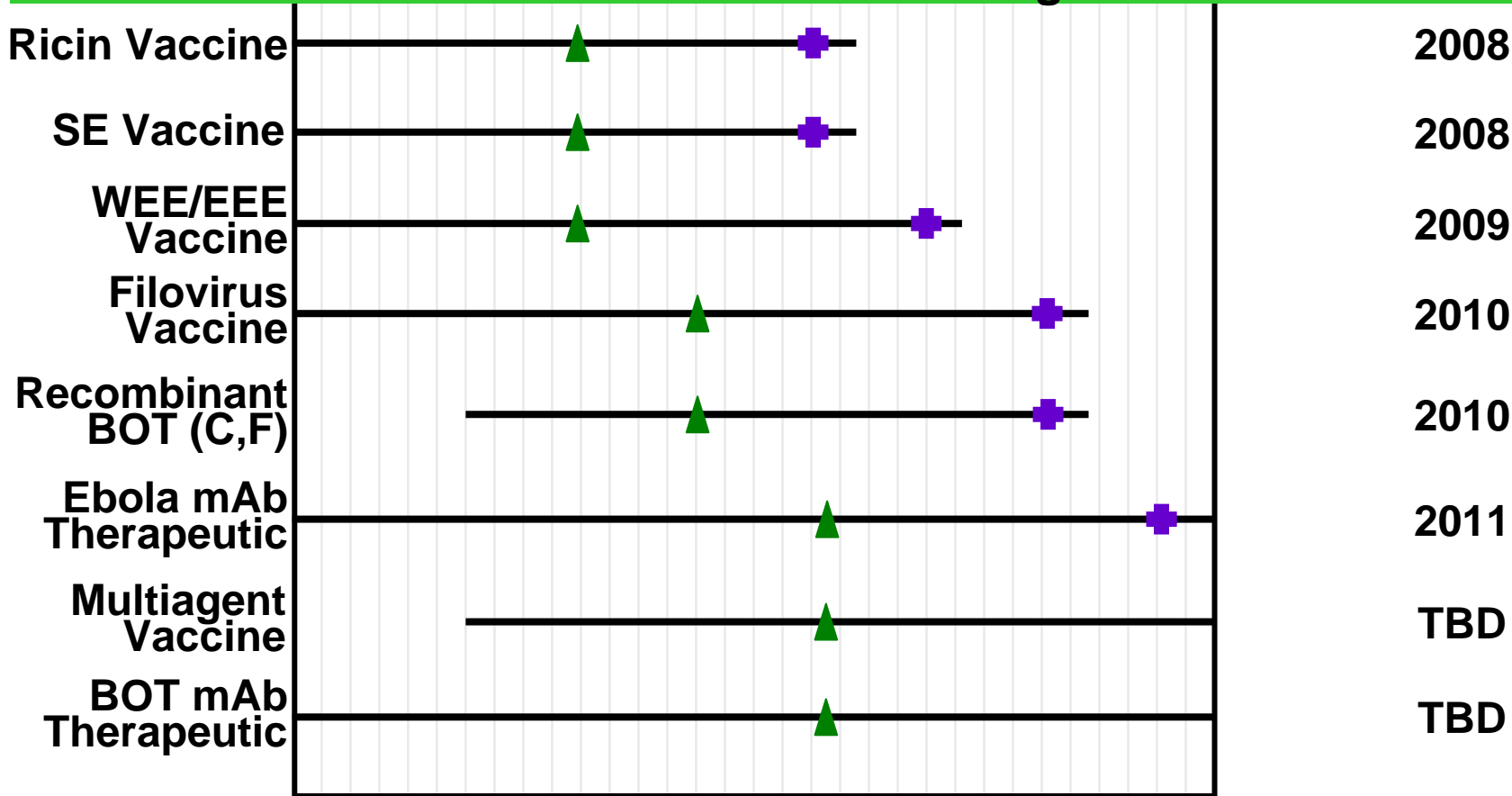


S&T Program Schedule



FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 Proposed Transition

JVAP DoD Funded Programs



LEGEND: ▲ Technology Transition Agreement (TTA) ■ Transition



S&T Program Schedule

FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 Proposed Transition

MIT S DoD Funded Programs

Bioscavenger Increment II



2006

Catalytic Bioscavenger Increment III



TBD

Orthopox Therapeutic



2008

Filovirus Therapeutic
(Nucleic Acid Based)



2008

BOT Therapeutics
(Small Compounds)



TBD

JBAIDS BLOCK II-A

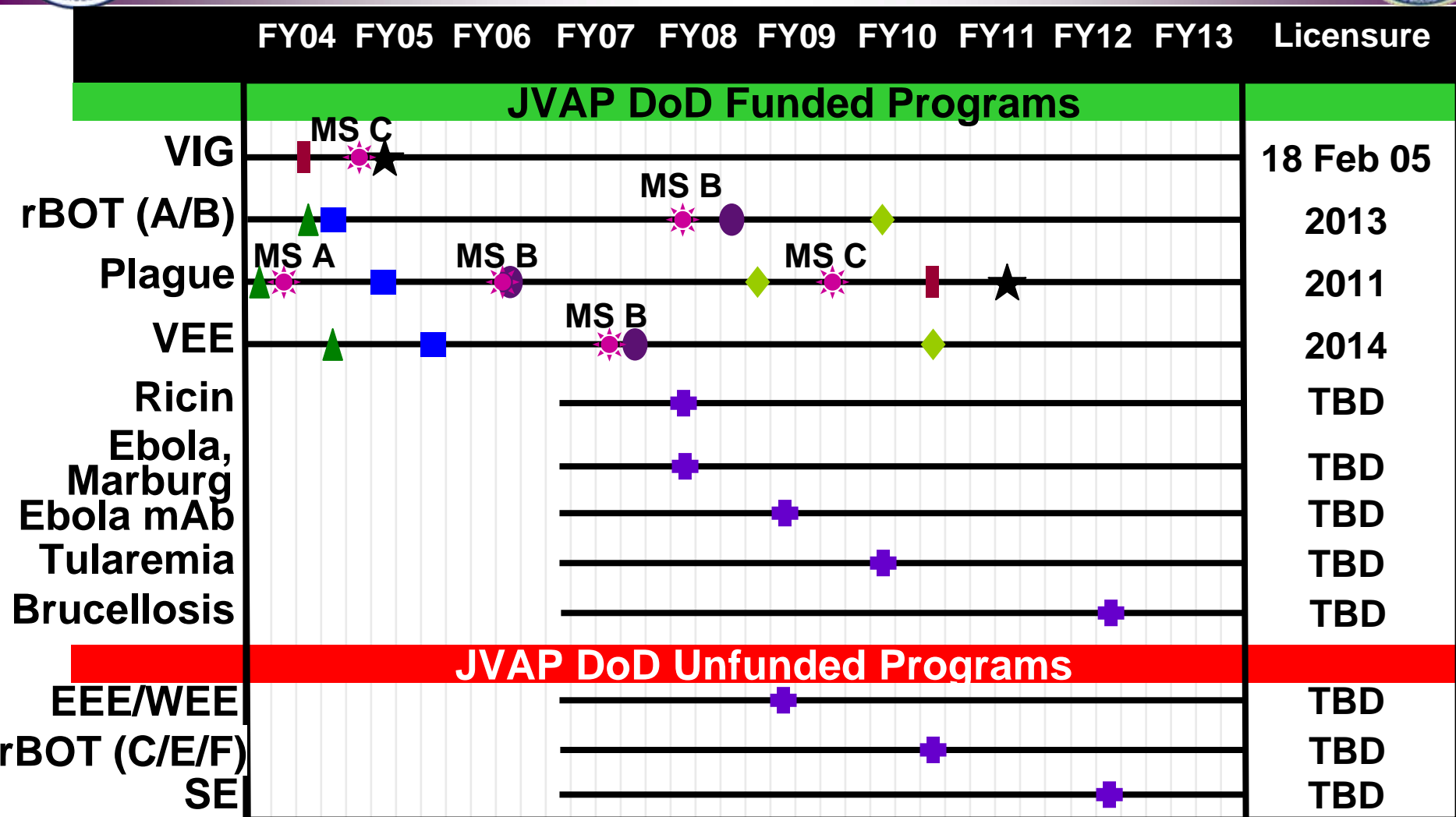


TBD

LEGEND: ▲ Technology Transition + Transition Agreement (TTA)



Program Schedule



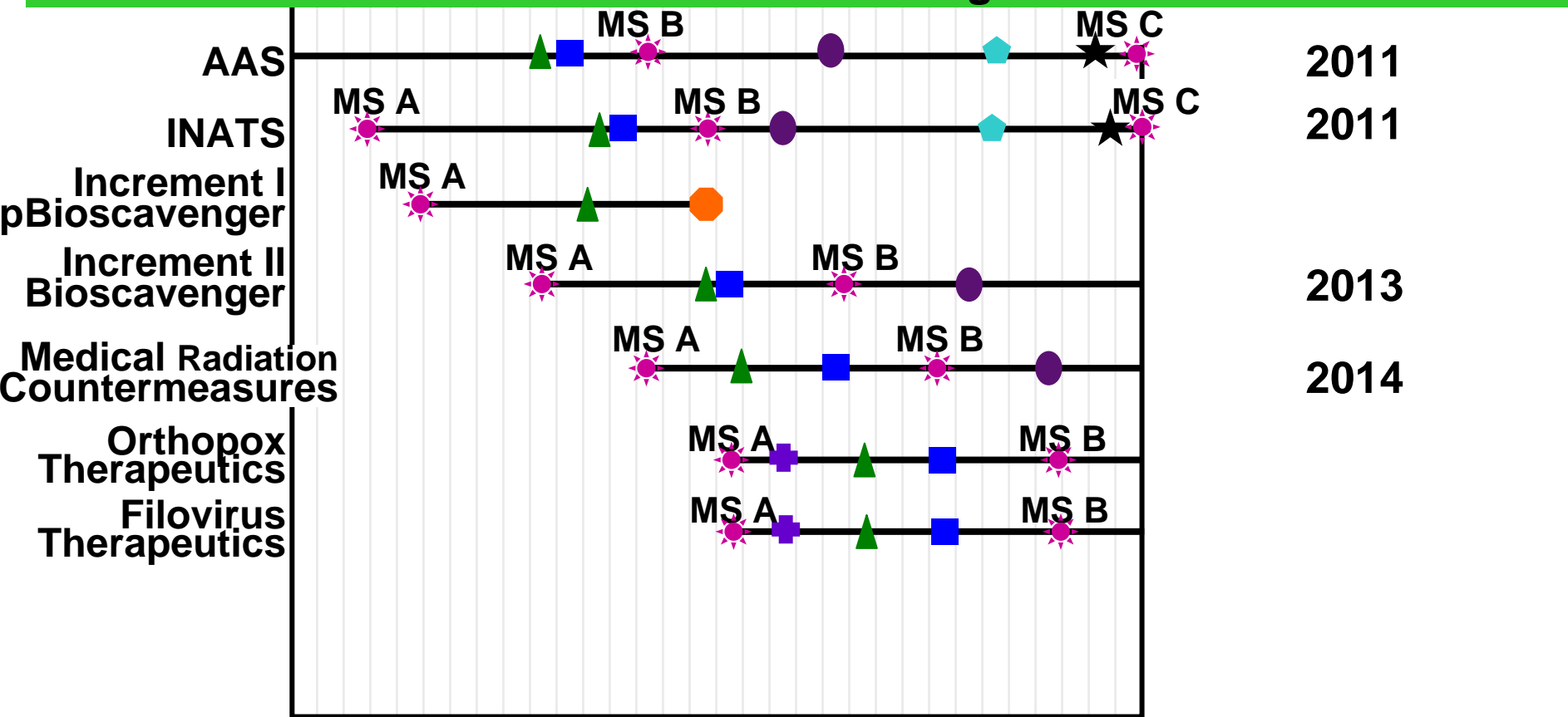
LEGEND:

- ☀ Milestone
- ▲ IND Submission
- Initiate Phase 1 Clinical Trial
- Initiate Phase 2 Clinical Trial
- ◆ Initiate Phase 3 Clinical Trial
- BLA Submission
- ★ Licensure
- ✚ Transition
- ◆ NDA Submission
- Transfer to DHHS

Program Schedule

FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 FDA Approval

MITS DoD Funded Programs



LEGEND:

- Milestone (Pink starburst)
- IND Submission (Green triangle)
- Initiate Phase 1 Clinical Trial (Blue square)
- Initiate Phase 2 Clinical Trial (Purple circle)
- Initiate Phase 3 Clinical Trial (Green diamond)
- BLA Submission (Red vertical bar)
- Licensure (Black star)
- Transition (Purple plus)
- NDA Submission (Cyan pentagon)
- Transfer to DHHS (Orange octagon)

Program Schedule

FY04 FY05 FY06 FY07 FY08 FY09 FY10 FY11 FDA Approval

MITS DoD Funded Programs

JBAIDS
BLOCK I

MS C



MITS DoD Unfunded Programs

JBAIDS
BLOCK II-A

MS A

MS B



LEGEND:

- Milestone
- Developmental Test
- Operational Test
- Initial Operational Capability
- FRP Decision
- Full Operational Capability
- Transition



S&T Funding



\$M	FY05	FY06	FY07	FY08	FY09	FY10	FY11	TOTAL
6.1 Research <i>(Core Program)</i>	30.4	37.6	31.7	38.4	36.2	32.3	30.7	237.3
6.1 TMTI		28.0	51.4	23.6	10.5	7.7	7.5	128.7
6.2 Research <i>(Core Program)</i>	40.9	94.7	68.6	73.3	74.0	72.9	71.1	495.5
6.2 TMTI		18.0	108.7	45.1	26.8	16.5	14.5	229.6
6.3 Research <i>(Core Program)</i>	69.1	82.7	52.8	64.4	64.8	73.9	76.5	484.2
6.3 TMTI		30.0	65	114.9	171.8	192.5	95.7	669.9
TOTAL	140.4	291.0	378.2	359.7	384.1	395.8	296.0	2245.2



Program Funding

\$M	FY05	FY06	FY07	FY08	FY09	FY10	FY11	TOTAL
MIT S								
BA4	9.2	21.8	44.7	30.3	20.2	16.1	8.8	150.9
BA5	11.2	19.2	19.8	48.9	33.7	19.1	20.2	172.1
PROC	20.2	23.1	8.0	17.3	13.7	11.2	2.7	96.4
Total	40.5	64.1	72.5	96.4	67.7	46.4	31.7	419.4
TMTI								
BA4	0.0	0.0	0.0	71.0	99.4	130.3	149.2	450.0
BA5	0.0	0.0	0.0	0.0	0.0	0.0	121.8	121.8
RDTE	0.0	0.0	0.0	71.0	99.4	130.3	271.1	571.8
JVAP								
BA4	13.7	12.6	0.0	0.0	0.0	8.2	17.0	51.5
BA5	15.8	46.0	58.4	81.8	90.8	72.3	51.1	416.2
PROC	80.4	38.4	39.1	14.5	42.4	41.8	31.8	288.4
Total	109.9	97.0	97.5	96.3	133.2	122.2	99.9	756.0



S&T Upcoming Business Opportunities



Program	Estimated Target BAA Release	Target Funding Year
Transformational Medical Technology Initiative – BAA	1Q/2QFY07 and TBD	FY07 – FY11
CB Defense Medical S&T Extramural Program – Tech Base – BAA	1QFY07	FY08
Small Business Innovation Research (SBIR) – Tech Base	1QFY07	FY06
Chem-Bio Defense Initiative Fund (CBDIF) – BAA	3QFY06	FY06



Program Upcoming Business Opportunities



Program	Description	Year	Estimated Contract Value
MITS			
AAS	RFP for Prime Contractor	4QFY06	\$15-25M
INATS	RFP for Prime Contractor	4QFY06	\$20-30M
Medical Radiation Countermeasures	RFP for Prime Contractor	1QFY07	\$40-50M
JVAP – subcontract through DVC			
Plague Vaccine	Multiple clinical site management for Plague vaccine Phase 2 clinical trial	3QFY06	Cost is evaluated separately from technical DVC's Award based on Best Value
Venezuelan Equine Encephalitis (VEE) Vaccine	NIAID-funded Phase 2 clinical trial	4QFY07	
Recombinant Botulinum (rBot) A/B Vaccine	Clinical site management for rBot vaccine Phase 1B clinical trial	4QFY06	



S&T Points of Contact



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- **Radiological Countermeasures**
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Advanced Development Points of Contact



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- **PM, Joint Vaccine Acquisition Program (JVAP)**
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- **DVC**
 - **Business Development:**
 - Harry Coffey, 301-607-5085
 - **Sr. Manager of Contracts:**
 - Susan Woolridge, 301-607-5009
 - **Acting Chief Executive Officer:**
 - Dale Luddeke, 301-607-5010