

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**





Warfighter Needs



- **Medical Priorities from the Chemical Biological Defense Program 2008 Joint Priority List (JPL)**
 - **FDA Approved**
 - **Prophylaxis**
 - Biological Prophylaxis
 - Chemical Prophylaxis
 - Radiological Prophylaxis
 - **Medical Diagnosis**
 - **Therapeutics**
 - Biological Therapeutics
 - Chemical Therapeutics
 - Radiological Therapeutics





Warfighter Needs



Requirements Identified

Acquisition Documents

- Initial Capabilities Document (ICD)
- Capabilities Development Document (CDD)
- Capabilities Production Document (CPD)
- Key Performance Parameter = FDA Licensure

ICD
 CDD
 CPD

Science & Technology (S&T) Development



Advanced Development

FDA Licensure Process





DTRA-JSTO Science & Technology (S&T) Overview



- Develop candidate pre-treatments/prophylaxes and therapeutics for protection against biological and chemical 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 candidate vaccines, drugs and diagnostic assays/devices to advanced development



DTRA-JSTO S&T Needs and Technical Challenges



Pretreatments:

- Novel vaccine platforms (including multi-valent and/or broad spectrum) effective against the bacterial threat agents
- Ability to predict/understand the human immune response to agents and/or vaccine candidates
- Alternate delivery technologies (i.e., to exploit DNA vaccines, needle-free, adjuvanted, etc.)
- Thermal stabilization methodologies
- Develop a catalytic or small molecule nerve agent prophylaxis

Therapeutics:

- Novel host-directed, broad-spectrum therapeutics
- Small molecule based antimicrobials targeting previously unexploited pathogen pathways
- Small molecule inhibitors of, and host-directed therapeutics effective against toxins
- Innovative therapeutic strategies and drug candidates to ameliorate the acute and long-lasting functional damage resulting from nerve agent intoxication
- Compounds that reactivate OP-inhibited AChE
- Therapeutic strategies that minimize injuries to dermal and ocular tissues resulting from CWAs



DTRA-JSTO S&T Needs and Technical Challenges



Diagnostics:

- NGDS that is small, portable and field deployable:
 - rapid, with improved sensitivity and specificity
 - multi-plexed & expandable
- Pre-analytical method refinement
- Early host-indicators/biomarkers of exposure/infection
- Ability to identify pathogens that exhibit high genetic plasticity
- Simultaneously indentify BW & non-BW pathogens in clinical matrices
- Integration of host response and pathogen-specific analyses on a single platform

Medical radiological defense:

- Develop effective radioprotectants (pretreatments and therapeutics); repair radiogenic damage to gastrointestinal tract
- Develop bio-dosimetry for MedRad exposure (deep tissue)

Animal models that will support the FDA licensure of candidate medical countermeasures using the animal rule

Multi-use platforms that can be utilized to develop candidate medical countermeasures against new and emerging threats



Program Overview Chemical Biological Medical Systems (CBMS)



Our Vision is a U.S. military force that is fully sustained to fight and win in any CBRN battle space worldwide



Our mission is to deliver safe, effective and robust medical products that protect U.S. forces against validated CBRN threats. We apply government and industry best practices to develop or acquire FDA-approved products within rigorously managed cost, schedule and performance constraints.



Current Advanced Development Efforts



- **CBMS products are integrated into the DoD “System of Systems” approach by providing the medical materiel solutions required to protect, diagnose and treat service members exposed to the effects of CBRN agents**
 - Joint Vaccine Acquisition Program (CBMS-JVAP)
 - “Develop, produce, and stockpile FDA-licensed vaccine systems to protect the Warfighter from biological agents”
 - Medical Identification & Treatment Systems (CBMS-MITS)
 - “Rapidly provide the Warfighter and the Nation robust and affordable FDA-approved lifesaving medical countermeasure drug and diagnostic system capabilities against chemical, biological, radiological and nuclear threats”
 - Biosurveillance (CBMS-BSV)
 - New program initiative within CBMS to leverage diagnostics expertise
 - CBMS serves as a “Trail boss” for efforts across JPEO-CBD



Current Advanced Development Efforts (cont.)



- **Biological Agent Prophylaxis**

- CBMS - JVAP partners with DynPort Vaccine Company (DVC) using the prime systems contractor approach to meet current DoD biological defense vaccine requirements for vaccines currently in development
 - DVC obtains and maintains FDA licenses
 - Recombinant Botulinum Toxin A / B Vaccine Program (rBV A / B)
 - Recombinant Plague Vaccine
- Transitioned new Filovirus Vaccine program to advanced development in 2010
 - Acquisition will be via full and open competition (manufacturing RFP release November 2010)

- **Chemical Agent Prophylaxis**

- Bioscavenger (exogenous human BChE) will prevent incapacitation and death from exposure to nerve agents



Current Advanced Development Efforts (cont.)



- **Medical Diagnosis**

- Joint Biological Agent Identification and Diagnostic System (JBAIDS) will provide portable diagnostic capability to warfighter.

Evolutionary approach:

- JBAIDS Increment I: System capable of identifying 10 Biological Warfare Agents (BWAs)
- Next Generation Diagnostic System
 - Capability will fully automate and integrate on-board sample preparation, analysis and identification, and reporting
 - Smaller and less complex system that will minimize consumables and laboratory support equipment
 - Interoperable with the global information grid and FDA-cleared for use as a diagnostic device
- Critical Reagents Program (CRP) provides biological threat agent and genomic reference material
 - Over 200 standards in inventory



Current Advanced Development Efforts (cont.)



- **Radiation Syndrome Therapeutics**
 - DoD Medical Radiation Countermeasure (MRADC)
 - Several countermeasures will be required to treat the range of acute radiation syndrome (ARS) injuries DoD currently focuses efforts on countering the Gastrointestinal sub-syndrome of Acute Radiation Syndrome (GI-ARS). DHS focuses on the hematopoietic sub-syndrome of ARS
- **Chemical Agent Therapeutics**
 - Advanced Anticonvulsant System (AAS) will replace Convulsant Antidote Nerve Agent (CANAs) system
 - Improved Nerve Agent Treatment System (INATS) active ingredient will replace and provide better protection than currently fielded oxime, 2-PAM
 - Inhalation Atropine (IA) will replace the expired Medical Aerosolized Nerve Agent Antidote (MANAA)



CBMS Technical Challenges



- **Leverage emerging technology to accelerate development**
- **Evolving FDA Guidance**
 - Animal Rule
 - Large scale manufacturing process validation
- **Industrial base / infrastructure sustainment**
- **Biosurety requirements for BSL 3 / 4 commercial facilities**
- **Product specifications must be fully compatible with medical logistics/sustainment needs of diverse military operations**
- **Enhance product thermostability / increased drug formulation stability**
- **Develop alternate delivery platforms to reduce number of injections**



S&T and CBMS-Warfighter 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**



DTRA-JSTO S&T Program Schedule / Transition to CBMS



FY04 **FY05** **FY06** **FY07** **FY08** **FY09** **FY10** **FY11** **FY12**
 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 1 2 3 4

**Proposed
Transition**

**Filovirus
Vaccine**



2010

**Portable
Genetic
Analyzer**



2011/12

Scopolamine



2012

**Maturation of
NGDS
technologies**

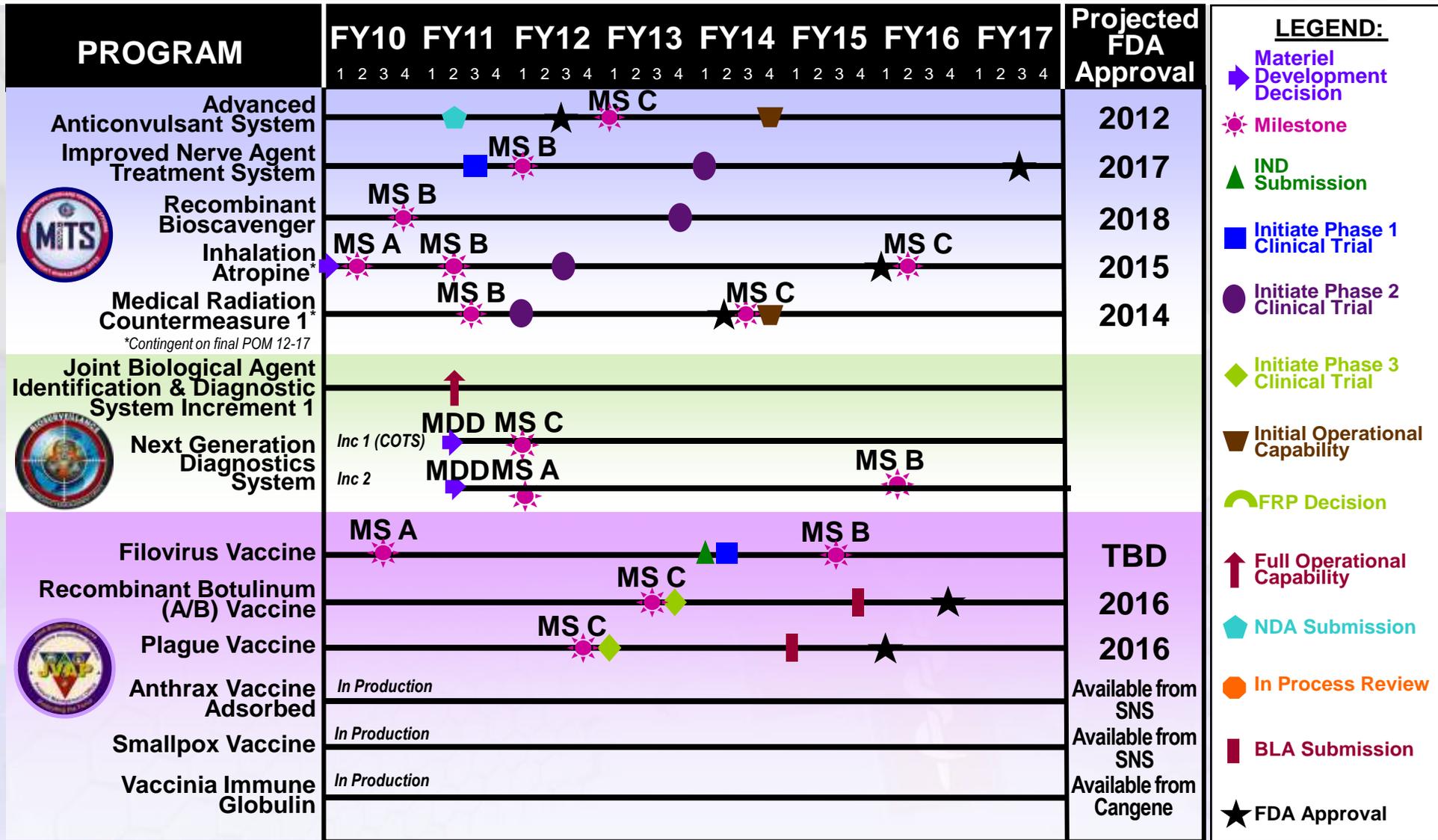


2012-14

LEGEND: ▲ **Technology Transition Agreement (TTA)** ✚ **Transition Opportunity**



CBMS: Current Efforts



- LEGEND:**
- Materiel Development Decision
 - Milestone
 - IND Submission
 - Initiate Phase 1 Clinical Trial
 - Initiate Phase 2 Clinical Trial
 - Initiate Phase 3 Clinical Trial
 - Initial Operational Capability
 - FRP Decision
 - Full Operational Capability
 - NDA Submission
 - In Process Review
 - BLA Submission
 - FDA Approval



DTRA-JSTO S&T Funding



\$M	FY12	FY13	FY14	FY15	TOTAL
6.2 Research <i>(Medical Core, CBM)</i>	75.5	77.7	78.8	80.1	312.1
6.3 Research <i>(Medical Core, CBM)</i>	74.7	69.9	72.5	73.6	290.7
TOTAL	150.2	147.6	151.3	153.7	602.8



CBMS FY10-16 Presidents Budget (FY11) Funding*



\$K	FY10	FY11	FY12	FY13	FY14	FY15	FY16	TOTAL
CBMS								
BA4/5	\$ 95,469	\$ 145,649	\$ 131,488	\$ 86,629	\$ 56,920	\$ 41,356	\$ -	\$ 557,511
PROC	\$ 12,701	\$ 19,389	\$ 4,378	\$ 8,925	\$ 70,996	\$ 109,891	\$ -	\$ 226,280
Total	\$ 108,170	\$ 165,038	\$ 135,866	\$ 95,554	\$ 127,916	\$ 151,247	\$ -	\$ 783,791

BA4 = Pre - Milestone B

BA5 = Post - Milestone B

**Data derived from FY11 BES (Presidents Budget) scenario.*



DTRA-JSTO S&T Upcoming Business Opportunities



Program	Estimated Target BAA Release	Target Funding Year
<p>DTRA Chemical & Biological Technologies Directorate FY12-13 2-yr Broad Agency Announcement (BAA)</p> <ul style="list-style-type: none"> •Extramural (non-US Government) only, leading to contract and grant awards •Additional topics may be added in the future; continue to monitor 	<p>FY12-13 Solicitation – <i>Open Now!</i></p>	<p>FY12 / 13</p>
<p>Small Business Innovation Research (SBIR) program</p> <ul style="list-style-type: none"> •Opportunity for Small Business engagement in S&T program •Lead to contract and grant awards <p>http://www.dodsbir.net/solicitation/default.htm</p>	<p>November 2010</p>	<p>FY11</p>
<p>Directed Research in DTRA CB Directorate</p>	<p>As Needed</p>	<p>Ongoing</p>
<p>DTRA R&D Innovation Office – Science and Technology New Initiatives BAA (HDTRA1-07-RDINO-BAA)</p>	<p>Open Now</p>	<p>Ongoing</p>
<p>DTRA Fundamental Research to Counter Weapons of Mass Destruction BAA (HDTRA1-09-14-FRCWMD-BAA)</p>	<p>Fall 2010</p>	<p>Ongoing</p>

Relevant Websites: <http://www.dtra.mil>, <http://www.fbo.gov>, <http://www.grants.gov>



Program Upcoming Business Opportunities



Program	Description	Year
<i>CBMS - Broad Agency Announcement</i>		
Broad Agency Announcement: Chemical Biological Medical Radiological and Nuclear Countermeasure Research & Development	http://www.smdc.army.mil/2008/CAMO-BAA.asp	Ongoing
<i>Dynport Vaccine Company</i>		
Botulinum Vaccine Program	Conduct Phase 3 clinical trial . Anticipated RFP release through DVC 3QFY11. http://www.csc.com/dvc	FY11-14
Plague Vaccine Program	Conduct Phase 3 clinical trials. Anticipated RFP release through DVC 2QFY11. http://www.csc.com/dvc	FY11-14
<i>Request For Proposal</i>		
Filovirus Vaccine Program	Process development, manufacturing, and Phase 1 clinical testing for filovirus vaccine (multiple RFPs anticipated) http://www.fbo.gov	FY10-15



Program Upcoming Business Opportunities (cont)



Program	Description	Year
<i>Request for Proposal</i>		
Centrally Acting Nerve Agent Therapeutic System (CANATS)	CANATS encompasses the addition of centrally-acting therapeutics to the current or future nerve agent antidote treatment regimens to improve the efficacy of these countermeasures against traditional nerve agents and NTAs. RFP anticipated in late FY12 for candidate development through Food and Drug Administration approval. http://www.fbo.gov	FY12-17
Improved Nerve Agent Treatment Systems	Advanced development of an improved oxime and additional indications for pyridostigmine bromide to support use against traditional and non-traditional nerve agents. Anticipated RFI release date 4QFY11; RFP release late FY12. www.fbo.gov	FY12-FY17
Next Generation Diagnostic	COTS procurement of Increment I of Next Generation Diagnostic System. Anticipated RFP release FY11. www.fbo.gov	FY12-FY16



Points of Contact



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CBMS Medical CBRN Broad Agency Announcement:

<http://www.smdc.army.mil/2008/CAMO-BAA.asp>

Defense Acquisition University: <http://www.dau.mil>