

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

# MEDICAL SYSTEMS

September 7, 2011

Advanced Planning  
Briefing to Industry



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# Agenda



- 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 2011 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)
- ✓ Capability Development Document (CDD)
- ✓ Capability Production Document (CPD)
- ✓ Key Performance Parameter = FDA Licensure

**Science & Technology (S&T) Development**



**Advanced Development**

**FDA Licensure Process**



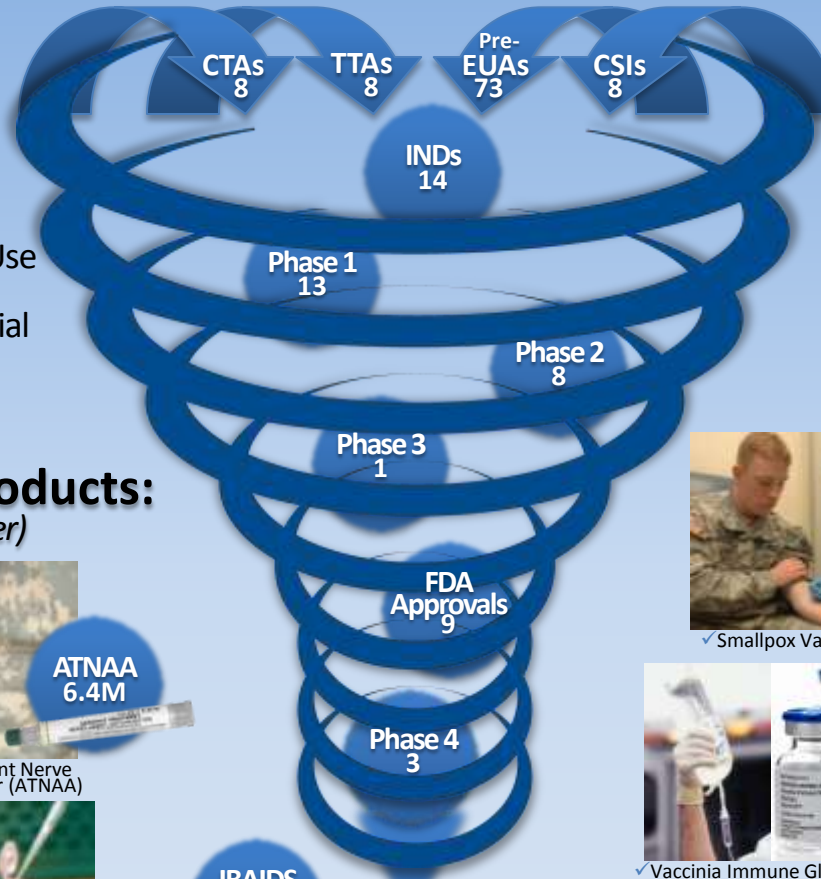


# Medical Capabilities Delivered to the Warfighter



## Partner Inputs:

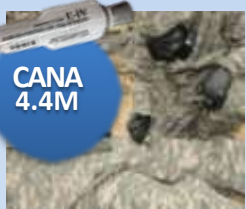
- ✓ 8 – Capability Transition Agreements (CTAs)
- ✓ 8 – Technology Transition Agreements (TTAs)
- ✓ 73 – Assays for Pre-Emergency Use Authorization (EUAs)
- ✓ 8 – Relevant Congressional Special Interest Projects (CSIs)



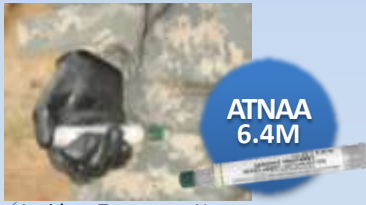
## CBMS Expertise:

- ✓ 14 - Investigational New Drugs (INDs)
- ✓ 13 – Phase 1 Clinical Trials
- ✓ 8 – Phase 2 Clinical Trials
- ✓ 1 – Phase 3 Clinical Trials
- ✓ 3 – Phase 4 Clinical Trials
- ✓ **9 - Food & Drug Administration (FDA) Approvals**

## Results in Fielded Products: (CBMS Lifecycle Manager)



✓ Convulsant Antidote for Nerve Agents (CANA)



✓ Antidote Treatment Nerve Agent Autoinjector (ATNAA)



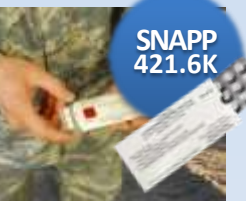
✓ Smallpox Vaccine (SPX)



✓ Anthrax Vaccine Adsorbed (AVA)



✓ Vaccinia Immune Globulin (VIG)



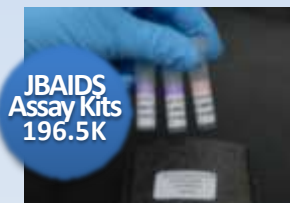
✓ Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP)



✓ Critical Reagents Program (CRP) Assay Kits: Electrochemiluminescence



✓ Joint Biological Agent Identification Diagnostic System (JBAIDS)



✓ Joint Biological Agent Identification Diagnostic System (JBAIDS)



✓ Critical Reagents Program (CRP) Assay Kits: Lateral Flow Immunoassays (LFI)



✓ Critical Reagents Program (CRP) Assay Kits: Polymerase-Chain Reaction (PCR)



# CBMS Successes



2001

Anthrax Vaccine Adsorbed

2003

Soman Nerve Agent Pretreatment Pyridostigmine\*

2003

Reactive Skin Decontamination Lotion\*

2003

Vaccinia Immune Globulin - Intravenous



2005

JBAIDS Anthrax Assay

2007

JBAIDS Tularemia Assay

2007

JBAIDS Plague Assay



2010

JBAIDS H5N1 Assay

2011

JBAIDS Q-Fever Assay



\*USAMRMC Transferred Product



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



- **Develop candidate pretreatments/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 Science & Technology (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)
- 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 Science & Technology (S&T) *Needs and Technical Challenges (cont.)*



- **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 identify 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 biodosimetry 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



# Chemical Biological Medical Systems (CBMS) *Program Overview*



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



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.



# CBMS 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 & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, biological, radiological and nuclear threats
  - Biosurveillance (CBMS-BSV)
    - Develop and integrate chemical, biological, radiological, and nuclear (CBRN) technologies to enable early warning, identification, and continued situational awareness of potential global health threats



# CBMS Current Advanced Development Efforts (cont.)

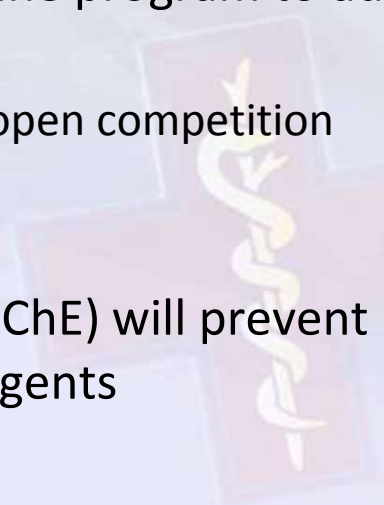


- **Biological Prophylaxis**

- 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

- **Chemical Prophylaxis**

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





# CBMS Current Advanced Development Efforts (cont.)



- **Medical Diagnostics**

- 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 is an evolutionary acquisition program that will provide increments of capability across the Combat Health Support, environmental surveillance and the CBRN Defense architecture
  - Platform components; FDA clearance for diagnostic components
  - Low complexity, low-resource components
  - Enabling components (screening, collection and preservation tools)
  - Range of threats include endemic, emerging and re-emerging Infectious Diseases (ID) of military importance and traditional and bio-engineered Biological Warfare Agents (BWA)
- Critical Reagents Program (CRP) provides biological threat agent and genomic reference material as well as assays for fielded systems
  - Over 200 strains in inventory



# CBMS Current Advanced Development Efforts (cont.)



- **Radiological Therapeutics**

- Medical Radiation Countermeasure (MRADC)

- Several countermeasures will be required to treat the spectrum of acute radiation syndrome (ARS) injuries
- DoD currently pursuing a gastrointestinal-ARS capability and will leverage HHS efforts on both GI- and hematopoietic sub-syndrome of ARS to fully meet broad spectrum protection

- **Chemical Therapeutics**

- Advanced Anticonvulsant System (AAS) will replace Convulsant Antidote Nerve Agent (CANA) system
- Improved Nerve Agent Treatment System (INATS) active ingredient will replace and provide better protection than the fielded oxime, 2-PAM



# 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 Science & Technology (S&T) Program Schedule/Transition to CBMS



**FY04** **FY05** **FY06** **FY07** **FY08** **FY09** **FY10** **FY11** **FY12**  
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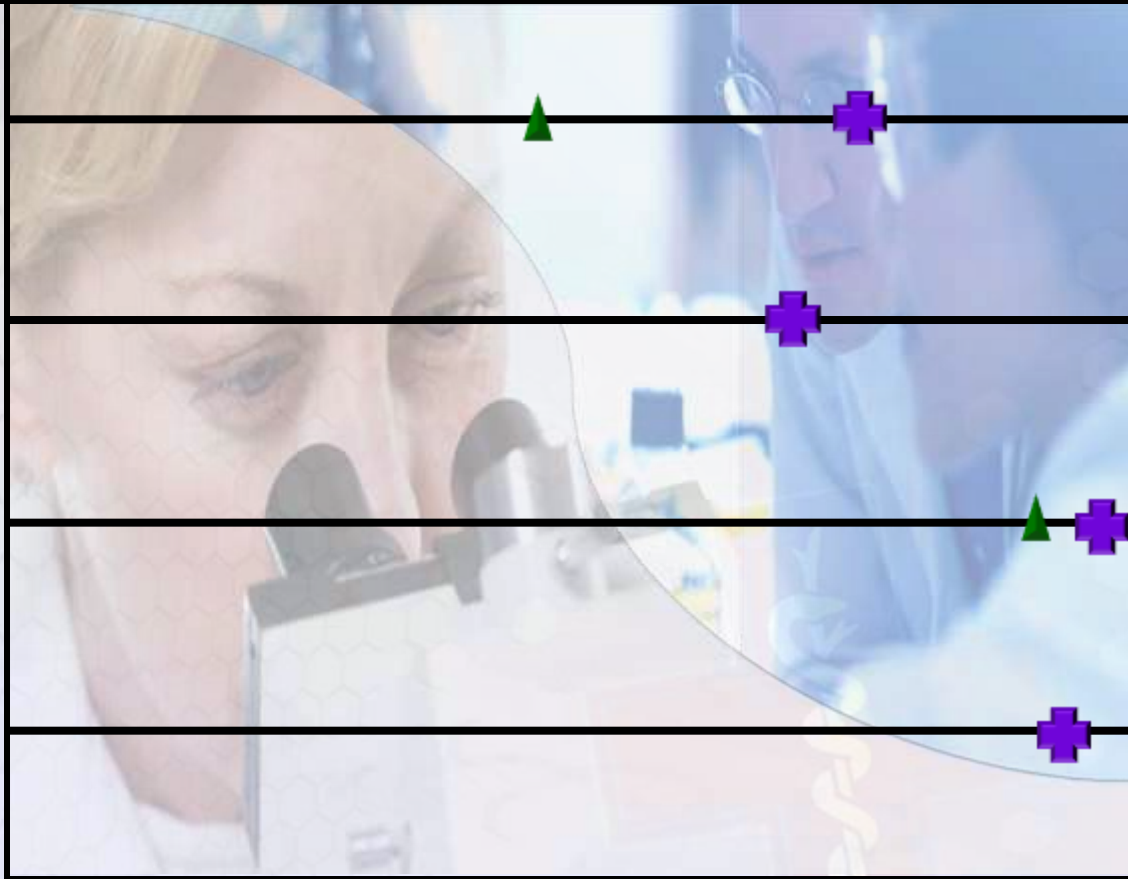
**Proposed  
Transition**

**Filovirus  
Vaccine**

**Portable  
Genetic  
Analyzer**

**Centrally Acting  
Nerve Agent  
Therapeutic**

**Maturation of  
NGDS  
Technologies**



**2010**

**2011/12**

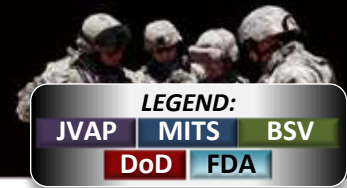
**2012**

**2012-14**

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



# CBMS Portfolio



**LEGEND:**

JVAP	MITS	BSV
DoD	FDA	

JPMs	CAPABILITY	PRODUCT	Development Phases										NEXT MS	LICENSURE	
			MDD	IND	PHASE 1	PHASE 2	PHASE 3	BLA/NDAs	APPROVAL	PROC	SUSTAIN	Next MS			
	Prophylaxis Vaccines	Filovirus Vaccine											MS B 2015	TBD	
		Recombinant Botulinum A/B Vaccine												MS C 2013	2016
		Plague Vaccine												MS C 2013	2016
		Anthrax Vaccine Adsorbed												★	SNS
		Smallpox Vaccine												★	SNS
		Vaccinia Immune Globulin												★	Cangene
	Pretreatment/Treatment Drugs	Advanced Anticonvulsant System											MS C 2013	2012	
		Bioscavenger												MS B 2012	2019
		Centrally Acting Nerve Agent Treatment System												MS A 2012	2020
		Improvement Nerve Agent Treatment System												MS B 2013	2017
		Inhalation Atropine												TBD	TBD
		Medical Radiation Countermeasures												MS B 2013	2016

JPMs	CAPABILITY	PRODUCT	Development Phases										NEXT MS	FIELD/ LICENSURE		
			MDD	DEVELOPMENT	PRE-CLINICAL	ANALYTICAL	CLINICAL	510(k)	REVIEW	PROC	SUSTAIN	Next MS				
	Devices Diagnostics & Reagents	Next Generation Diagnostic System— Increment 1												MS A 2012	TBD	
		Next Generation Diagnostic System— Increment 2													MS A 2013	TBD
		Joint Biological Agent Identification & Diagnostic System												★	Services	
		◆ Diagnostic Kit: Expanded Influenza Panel												510(k)	2011	
		◆ Diagnostic Kit: Glanders												510(k)	2014	
		◆ Diagnostic Kit: Typhus												510(k)	2013	
		◆ 510(k) Amendments: Anthrax, Plague & Tularemia												510(k)	2013	
◆ Diagnostic Kits: Anthrax, Tularemia, Plague, Avian Influenza (Flu A/H5), Q-Fever												★	Services			



# DTRA-JSTO Science & Technology (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
<b>TOTAL</b>	<b>150.2</b>	<b>147.6</b>	<b>151.3</b>	<b>153.7</b>	<b>602.8</b>





# CBMS FY11-17 Presidents Budget (FY12) Funding\*



\$K	FY11	FY12	FY13	FY14	FY15	FY16	FY17	TOTAL
<b>CBMS</b>								
<b>BA4/5/7</b>	\$ 145,649	\$ 181,222	\$ 174,922	\$ 209,085	\$ 116,040	\$ 92,431	\$ 52,767	\$ 972,116
<b>PROC</b>	\$ 19,389	\$ 1,001	\$ 36,326	\$ 28,106	\$ 29,597	\$ 26,790	\$ 49,738	\$ 190,947
<b>Total</b>	\$ 165,038	\$ 182,223	\$ 211,248	\$ 237,191	\$ 145,637	\$ 119,221	\$ 102,505	\$ 1,163,063

**BA4 = Pre-Milestone B**

**BA5 = Post-Milestone B**



\*Data derived from FY12 BES (Presidents Budget) scenario.



# DTRA-JSTO S&T Upcoming Business Opportunities



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

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



# CBMS Program Upcoming Business Opportunities



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



# CBMS Program Upcoming Business Opportunities (cont.)



Program	Description	Year
<i>Request for Proposal</i>		
<b>Centrally Acting Nerve Agent Treatment System (CANATS)</b>	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. RFI release 2QFY12 and RFP anticipated 1QFY13 for candidate development through Food and Drug Administration approval. <a href="http://www.fbo.gov">http://www.fbo.gov</a>	<b>FY13-20</b>
<b>Improved Nerve Agent Treatment Systems (INATS)</b>	Advanced development of an improved oxime and additional indications for pyridostigmine bromide to support use against traditional nerve agents and NTAs. Anticipated RFI release date 2QFY12; RFP release late FY12. <a href="http://www.fbo.gov">www.fbo.gov</a>	<b>FY12-FY17</b>
<b>Bioscavenger</b>	Advanced development of plasma butyrylcholinesterase as a nerve agent prophylactic to include manufacturing, clinical and non-clinical trials. Anticipated draft RFP for Industry comment early 1QFY12 and RFP release 2QFY12. <a href="http://www.fbo.gov">www.fbo.gov</a>	<b>FY12-FY19</b>
<b>Next Generation Diagnostic System (NGDS)</b>	COTS procurement of Increment I of Next Generation Diagnostic System. Anticipated RFP release FY12. <a href="http://www.fbo.gov">www.fbo.gov</a>	<b>FY12-FY16</b>



# 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>