Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Countermeasure Systems (MCS)

Command Overview Briefing

Presented at:
Other Transaction Authority Industry Day

COL Russell E. Coleman
Joint Project Manager
Medical Countermeasure Systems
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June 15, 2015

DISTRIBUTION STATEMENT A: APPROVED FOR PUBLIC RELEASE. DISTRIBUTION IS UNLIMITED.
• MCS wants to gather information regarding the use of Other Transaction Authority (OTA) consortium approach
  – What *incentives can we offer* to entice Non-Traditional Defense Contractors to work with the DoD in an OTA consortium approach?
  – What *issues must be solved* to develop a successful OTA consortium approach?
  – Is there *another approach* that will *provide a better solution*?

How can we work with you? Ask questions?
WHO WE ARE
Medical Countermeasure Systems (MCS)

VISION
A U.S. military force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide

MISSION
To provide U.S. military forces and the nation safe, effective, and innovative medical solutions to counter CBRN threats
Spectrum of Medical Countermeasures (MCM)

PROPHYLAXIS SUSTAINS THE FORCE

DIAGNOSTIC IDENTIFIES THREATS TO TREAT

THERAPEUTIC SAVES LIVES
WHAT WE DO
## Products in the Pipeline

**PREVENTION**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MDD</th>
<th>MS A</th>
<th>MS B</th>
<th>MS C (LRIP)</th>
<th>NEXT MS</th>
<th>FDA LICENSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombinant Botulinum A/B Vaccine</td>
<td></td>
<td></td>
<td></td>
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<td>MS C 2017</td>
<td>2022</td>
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<td>Plague Vaccine</td>
<td></td>
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<td>MS C 2015</td>
<td>2019</td>
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<tr>
<td>Bioscavenger</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MS C 2019</td>
<td>2020</td>
</tr>
<tr>
<td>Filovirus Vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MS B 2017</td>
<td>2025</td>
</tr>
<tr>
<td>Ricin Vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MS B TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>WEVEE Vaccine</td>
<td></td>
<td></td>
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<td></td>
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<td>2029</td>
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**DIAGNOSTICS**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MDD</th>
<th>MS A</th>
<th>MS B</th>
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<tr>
<td>Next Generation Diagnostic System – Increment 1</td>
<td></td>
<td></td>
<td></td>
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<td>2017</td>
</tr>
<tr>
<td>Next Generation Diagnostic System – Increment 2</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>JBAIDS Pre-EUA Kits: Typhus, Burkholderia/Melioidosis</td>
<td></td>
<td></td>
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<td></td>
<td>Pre-EUA</td>
<td>2014</td>
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<tr>
<td>JBAIDS Food &amp; Water Pathogens</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2014</td>
<td>N/A</td>
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**THERAPEUTICS**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>MDD</th>
<th>MS A</th>
<th>MS B</th>
<th>MS C (LRIP)</th>
<th>NEXT MS</th>
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<tbody>
<tr>
<td>Advanced Anticonvulsant System</td>
<td></td>
<td></td>
<td></td>
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<td>FRP 2017</td>
<td>2017</td>
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<tr>
<td>Emerging Infectious Disease (EID) Therapeutics – Flu</td>
<td></td>
<td></td>
<td></td>
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<td>MS C 2016</td>
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<td>Hemorrhagic Fever Virus (HFV) Therapeutic</td>
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<td>MS B 2015</td>
<td>2021</td>
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<tr>
<td>EID Therapeutics – New Indication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MS C 2021</td>
<td>2022</td>
</tr>
<tr>
<td>Improved Nerve Agent Treatment System</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>MS B 2017</td>
<td>2021</td>
</tr>
</tbody>
</table>

As of Date: 01/09/15

Legends:
- MDD = Material Decision Document
- MS = Milestone
- LRIP = Low Rate Initial Production
- FRP = Full Rate Production
- EUA = Emergency Use Authorization
# Products Fielded

## CAPABILITY: PREVENTION

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>FDA LICENSURE</th>
<th>FY02-12</th>
<th>FY13</th>
<th>FY14</th>
<th>TOTAL</th>
</tr>
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<tbody>
<tr>
<td>Anthrax Vaccine Adsorbed</td>
<td>2002</td>
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<td>.52 M</td>
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<tr>
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<td>2005</td>
<td>288</td>
<td>240</td>
<td>0</td>
<td>528</td>
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</table>

## CAPABILITY: DIAGNOSTICS

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<th>PRODUCT</th>
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<th>FY02-12</th>
<th>FY13</th>
<th>FY14</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joint Biological Agent Identification &amp; Diagnostic System (JBAIDS)</td>
<td>2005</td>
<td>340</td>
<td>0</td>
<td>0</td>
<td>340</td>
</tr>
<tr>
<td>JBAIDS Assay Kits</td>
<td>2005-11</td>
<td>22.8 K</td>
<td>2.29 K</td>
<td>1.30 K</td>
<td>26.4 K</td>
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</table>

## CAPABILITY: THERAPEUTICS

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>FDA APPROVAL</th>
<th>FY02-12</th>
<th>FY13</th>
<th>FY14</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidote Treatment Nerve Agent Autoinjector (ATNAA)</td>
<td>2002</td>
<td>9.7 M</td>
<td>.28 M</td>
<td>0</td>
<td>9.9 M</td>
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<tr>
<td>Convulsant Antidote Nerve Agents (CANA)</td>
<td>1990</td>
<td>5.2 M</td>
<td>.13 M</td>
<td>.02 M</td>
<td>5.3 M</td>
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<tr>
<td>Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP)</td>
<td>2003</td>
<td>.49 M</td>
<td>.03 M</td>
<td>.01 M</td>
<td>.53 M</td>
</tr>
</tbody>
</table>

**LEGEND:**
- PREVENTION
- DIAGNOSTICS
- THERAPEUTICS

**NUMBER OF PRODUCTS DELIVERED**

As of Date: 01/09/15
DoD: Meeting the Needs of the Warfighter

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

**Translational Teamings**
- Capability Technology Agreement (CTA)
- Technology Transition Agreement (TTA)

SAFE & EFFECTIVE FDA APPROVED PRODUCTS
## Integration of the DoD and FDA Product Development Models

<table>
<thead>
<tr>
<th>DoD</th>
<th>FDA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MRL 1-4</strong></td>
<td><strong>MRL 5-6</strong></td>
</tr>
<tr>
<td>TRL 1-4</td>
<td>TRL 5-6</td>
</tr>
<tr>
<td><strong>Material Solution Analysis</strong></td>
<td><strong>Technology Development</strong></td>
</tr>
<tr>
<td><strong>Research/Discovery</strong></td>
<td><strong>Pre-Clinical/Clinical Development</strong></td>
</tr>
<tr>
<td><strong>Lab Scale Production</strong></td>
<td><strong>Process Development &amp; Pilot Lot Production</strong></td>
</tr>
<tr>
<td><strong>Initial Assay Development</strong></td>
<td><strong>Manufacturing Scale Up</strong></td>
</tr>
<tr>
<td><strong>Proof of Concept Animal Studies</strong></td>
<td><strong>Clinical Assay Development</strong></td>
</tr>
<tr>
<td><strong>Milestone A</strong></td>
<td><strong>Phase 1 Human Trials (safety)</strong></td>
</tr>
<tr>
<td><strong>Milestone B</strong></td>
<td><strong>Phase 2 Human Trials (safety/dose/schedule)</strong></td>
</tr>
<tr>
<td><strong>Milestone C LRIP (Vaccines)</strong></td>
<td><strong>Phase 3 Human Trials (expanded safety)</strong></td>
</tr>
<tr>
<td><strong>Milestone C FRP (Drugs)</strong></td>
<td><strong>Pivotal Animal Efficacy Studies</strong></td>
</tr>
<tr>
<td><strong>Emergency Use Authorization (EUA) May Be Considered</strong></td>
<td><strong>Biologic License Agreement (BLA/NDA)</strong></td>
</tr>
<tr>
<td><strong>DoD</strong></td>
<td><strong>FDA</strong></td>
</tr>
<tr>
<td><strong>MRL 7-8</strong></td>
<td><strong>MRL 9</strong></td>
</tr>
<tr>
<td>TRL 7</td>
<td>TRL 8</td>
</tr>
<tr>
<td><strong>Engineering &amp; Manufacturing Development</strong></td>
<td><strong>Production &amp; Deployment</strong></td>
</tr>
<tr>
<td><strong>Clinical Development</strong></td>
<td><strong>Regulatory Submission</strong></td>
</tr>
<tr>
<td><strong>Validation &amp; Demo Lots</strong></td>
<td><strong>Post Licensure</strong></td>
</tr>
<tr>
<td><strong>Consistency Lots</strong></td>
<td><strong>FDA Review</strong></td>
</tr>
<tr>
<td><strong>Pivotal Animal Efficacy Studies</strong></td>
<td><strong>Phase 4 Post Marketing Surveillance</strong></td>
</tr>
<tr>
<td><strong>BLA/NDA</strong></td>
<td><strong>Stockpile</strong></td>
</tr>
<tr>
<td><strong>FDA Review</strong></td>
<td><strong>Sustain</strong></td>
</tr>
<tr>
<td><strong>Material Decision Document (MDD)</strong></td>
<td><strong>Initial Operational Capability</strong></td>
</tr>
<tr>
<td><strong>Department of Defense (DoD)</strong></td>
<td><strong>Full Operational Capability</strong></td>
</tr>
<tr>
<td><strong>Food &amp; Drug Administration (FDA)</strong></td>
<td><strong>Full Rate Production</strong></td>
</tr>
</tbody>
</table>

### LEGEND:
- MRL = Manufacturing Readiness Levels
- TRL = Technology Readiness Levels

Reference: DoD 5000.02 Interim Nov 13
Product Development and the Animal Rule

TRADITIONAL LICENSURE PATHWAY

ANIMAL RULE LICENSURE PATHWAY

• Allows for approval of products for which efficacy testing in humans is unethical
• Extensive Animal Model and Assay Development
  – Efficacy is demonstrated in more than one, well defined animal model
  – Well controlled animal studies provide data that are likely to predict a benefit in humans
  – Greater emphasis and reliance placed upon validated assays for demonstration of efficacy

Animal Rule Citation: 21 CFR Parts 314 and 601; New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible
WHAT ARE WE DOING TO IMPROVE
Enhancing Stakeholder Partnerships

**INDUSTRY**
- Experienced Pharma
- Dedicated Prime Contractors
- Small Biotechnology Companies
- Others

**INTERAGENCY**
- Health and Human Services
- Department of Homeland Security
- Food & Drug Administration
- Centers for Disease Control

**INTRA-AGENCY**
- OTSG-U.S. Army
- ASD-Health Affairs
- DTRA-JSTO
- USAMRMC
- AFRRI
- U.S. AFHS
- Service Laboratories
- Service Hospitals
- DARPA

**INTERNATIONAL**
- Medical Countermeasure Consortium (MCMC) – US/UK/CAN/AUS

**ACADEMIA**
- Academic Labs and Research Institutions
- University-led Drug Discovery Centers and Programs

**CONGRESS**
- Congressional Special Interests
- University Affiliated Research Centers
Enhancing Industry Partnerships

• We are developing products that we hope will never be used and for which the threat is totally unpredictable (don’t know what, where, when or how much)

• Poor ROI makes it difficult to attract “right” partners, even when we pay all R&D costs

• We are trying to better understand the incentives/disincentives that affect industry decisions on working with us:
  – MCM OTA Consortium
  – Working with Tuft’s Center for the Study of Drug Development to bring together an expert panel to make recommendations on incentivizing industry (e.g., FDA priority voucher-like incentives)
Summary

• What *incentives can we offer* to entice Non-Traditional Defense Contractors to work with the DoD in an OTA consortium approach?

• What *issues must be solved* to develop a successful OTA consortium approach?

• Is there *another approach* that will *provide a better solution*?
Contact Us

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Fort Belvoir, VA 22060-5865
703-704-2374
Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Countermeasure Systems (MCS)-Diagnostics (Dx)

Diagnostics Portfolio Briefing

Presented at:
Other Transaction Authority Industry Day

Jason Opdyke, Ph.D.
Senior Scientist, Diagnostics
Tauri Group Support
Medical Countermeasure Systems
jason.opdyke.ctr@mail.mil

June 15, 2015
Mission
Develop, acquire, integrate, and field identification technologies and FDA-cleared diagnostic devices intended for Service Members to aid in the early diagnosis, prevention, and treatment of the effects of exposure to chemical, biological, and radiological (CBR) agents.
MCS-Diagnostics

• Current products and programs
  – Joint Biological Agent Identification and Diagnostic System (JBAIDS) lifecycle management: Fielded
  – Joint Handheld Biological Identifier (JHBI)
  – Next Generation Diagnostics System (NGDS) Increment 1: MS C FY16
  – NGDS Increment 2: Preparation for milestone (MS) B FY16
Joint Biological Agent Identification and Diagnostic System (JBAIDS)

Ruggedized mobile laboratory analytical system that provides rapid and highly accurate identification of multiple biological agents in clinical, food, and environmental samples

- Anthrax Assay
- Plague Assay
- Tularemia Assay
- H5N1 Avian Flu Assay
- Q-Fever Assay
- Influenza A&B Typing Assay
- Influenza A Subtype Assay

Environmental Surveillance Assays

Next Generation Diagnostics System (NGDS) Increment 1

Description:
Common medical test equipment and diagnostic platform for multiple biological threat agents, automated and integrated across all levels of the military health system.

Last Milestone:
MS A, Feb 2012

Clinical / FDA Accomplishment:
- Authorized Emergency Use Authorization (EUA) for NGDS Bio Threat-Ebola panel

Next Steps:
- **DoD**
  - Next Acquisition MS: MS C, FY16
  - Next Clinical MS: 510(k)
  - Projected FDA Clearance Date: FY16

- **FDA**
## Next Generation Diagnostics System (NGDS) Increment 2

<table>
<thead>
<tr>
<th>Description</th>
<th>Common medical test equipment &amp; diagnostic platform. Expand breadth of Inc 1 diagnostics capability to difficult pathogens, toxins, traditional Chemical Warfare Agents, non-traditional agents and radiation exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Milestone</td>
<td>Material Development Decision (MDD)</td>
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<tr>
<td>Clinical / FDA Accomplishment</td>
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<tr>
<td>Next Steps</td>
<td></td>
</tr>
</tbody>
</table>
| DoD | →Next Acquisition MS: MS B FY16  
| FDA | →Next Clinical MS: N/A  
|  | →Projected FDA Clearance Date: TBD |

Milestone = MS

### Business Opportunities

- Request for proposal (RFP) anticipated 1QFY16 for a diagnostic platform
  - Desired features of such systems include high sensitivity and specificity,  
  - Ease of use (Clinical Laboratory Improvement Amendments (CLIA) waiver),  
  - Multiplexing capability,  
  - Integrated sample preparation, and low logistics burden,  
  - A single system that could integrate multiple detection technologies is preferred
# Joint Hand-held Biological Identifier Increment 1

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Provide the capability to rapidly and accurately identify bio-agents at the point of contact from environmental samples with a handheld device</td>
<td></td>
</tr>
<tr>
<td>Last Milestone</td>
<td>MS B, Mar 2015</td>
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<tr>
<td>Clinical / FDA Accomplishment</td>
<td>NA</td>
</tr>
<tr>
<td>Next Steps</td>
<td></td>
</tr>
<tr>
<td>DoD</td>
<td>→ Next Acquisition MS: MS C, FY16</td>
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<tr>
<td>FDA</td>
<td>→ Next Clinical MS: N/A; environmental identifier</td>
</tr>
<tr>
<td></td>
<td>→ Projected FDA Clearance Date: NA</td>
</tr>
</tbody>
</table>

- **Business Opportunities**
  - RFP anticipated in 4QFY15/1QFY16 to support polymerase chain reaction assay manufacture for peace-time and surge capabilities.
Discussion

- MCS-Dx wants to gather information regarding the use of Other Transaction Authority (OTA) consortium approach
  - What *incentives can we offer* to entice Non-Traditional Defense *diagnostics developers* to work with the DoD in an OTA consortium approach?
  - What *issues must be solved* to develop a successful OTA consortium approach?
  - Is there *another approach* that will *provide a better solution*?

How can we work with you? Ask questions?
Contact Us

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Medical Countermeasure Systems (MCS)  
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Email: [jennifer.c.dabisch.civ@mail.mil](mailto:jennifer.c.dabisch.civ@mail.mil)

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**Senior Scientist**  
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Contractor Support, Tauri Group  
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Medical Countermeasure Systems (MCS)-Joint Vaccine Acquisition Program (JVAP)

Vaccines Portfolio Briefing

Presented at:

Other Transaction Authority Industry Day

LTC Victor Suarez
Joint Product Manager
Joint Vaccine Acquisition Program (JVAP)
victor.a.suarez.mil@mail.mil

June 15, 2015
Agenda

- JVAP Mission and Vision
- Integrating DoD and FDA product development models
- Products Fielded and in the Pipeline
- Program Overviews
- Biological Prophylaxis Technology Needs
MCS-Joint Vaccine Acquisition Program (MCS-JVAP)

**Mission**
Develop, produce & field FDA-licensed vaccine systems to protect the Warfighter from biological agents

**Vision**
Be the Joint Warfighter’s and the Nation’s first choice for advanced development of vaccine products which protect our military and partners from biological agents
# Products Fielded and in the Pipeline

## Table: Number of Products Delivered by FY

<table>
<thead>
<tr>
<th>CAPABILITY</th>
<th>PRODUCT</th>
<th>FDA LICENSURE</th>
<th>FY02-12</th>
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<td>288</td>
<td>240</td>
<td>0*</td>
<td>528</td>
</tr>
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</table>

## Table: FDA Approval Timeline

<table>
<thead>
<tr>
<th>CAPABILITY</th>
<th>PRODUCT</th>
<th>IND</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>BLA</th>
<th>NEXT MS</th>
<th>FDA LICENSURE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Filovirus Vaccine</td>
<td>2016</td>
<td>2017</td>
<td>2020</td>
<td>2023</td>
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</tr>
<tr>
<td></td>
<td>Ricin Vaccine</td>
<td>Jan 2014</td>
<td>2016</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
<td>MS B TBD</td>
<td>TBD</td>
</tr>
<tr>
<td></td>
<td>WEVIEE Vaccine</td>
<td>2017</td>
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<td>2024</td>
<td>2027</td>
<td>2028</td>
<td>GS B 2019</td>
<td>2029</td>
</tr>
</tbody>
</table>

*Note: JVAP fielded 240 treatment doses of VIGIV in early FY15 (4 Oct 15)
Program Description

- Botulinum Vaccine will be a Food and Drug Administration-licensed product to protect against aerosolized exposure to botulinum neurotoxins serotypes A and B
- **Contractors:** DynPort Vaccine Company, Frederick, MD; Battelle, W. Jefferson, OH; Jubilant, Hollister Stier, Spokane, WA; FUJIFILM Diosynth Biotechnologies (FDBU), Morrisville, NC
- **Contract Type:** Cost Plus Award Fee
- **IOC/FOC:** 150K / 500K TEDs* Draft CPD
  *TED=Troop Equivalent Dose

Recent Milestones or Events

- AUG 14 - Revised APB approved by MDA
- NOV 14 - Pivotal animal study report complete
- JAN 15 - CWMD WG Tripwire-endorsed APB
- Feb 15 - Antigen B Feasibility runs completed at new CMO
- Mar 15 - FCB Tripwire brief-endorsed APB to JCB

Near Term Milestones or Events

- 3QFY15 - Antigen A Technology Transfer FMEA
- 3QFY15 - Antigen B DOE initiated
- 4QFY15 - Antigen A development runs

Threat Overview

- One of the most lethal nerve toxins known (50-100 times more toxic than sodium cyanide)
- Estimated 1 gram of crystalline toxin, evenly dispersed and inhaled, has potential to kill 1.5M people
- Treatment without vaccination requires enormous demands on intensive medical care
- Historical use as BWA includes: Russia and Iraq stockpiled BOT Toxin up to 20,000 liters, enough to kill earth’s entire population
- Japanese Cult Aum Shinrikyo attempted to use Botulinum Toxin on several occasions between 1990-1995 in Japan

Vaccine Manager: MAJ John Nuckols
Plague Vaccine

Program Description

- Plague Vaccine will prevent pneumonic plague from aerosolized exposure to the bacteria *Yersinia pestis*.
- **Contractors:** DynPort Vaccine Company, Frederick MD; Jubilant, Hollister Stier, Spokane, WA; FUJIFILM Diosynth Biotechnologies (FDBU), Morrisville, NC
- **Contract Type:** Cost Plus Award Fee
- **IOC/FOC:** 150K / 410K TEDs* Draft CPD

*TED=Troop Equivalent Dose

Plague Vaccine Schedule

<table>
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<td>Pivotal Animal Efficacy</td>
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</table>

Recent Milestones or Events

- Nov 14 – Completion of studies to demonstrate that human antibodies to plague provide full protection against aerosol infection
- Feb 15 - FDA acceptance of Cynomolgus macaques as primary animal model for pivotal efficacy studies
- Mar 15 – FDA concurred with parallel pivotal animal study w/ Phase 3 trial, non-clinical approach to determine efficacy in humans and efficacy statistical approach

Near Term Milestones or Events

- 1QFY16 – End of Phase 2 meeting with FDA
- 1QFY16 – CMC drug substance submission to FDA

Threat Overview

- Threat due to historical evidence of its use as a BWA (Japan WWII, Russia developed offensive plague capabilities). Natural outbreaks still occur world-wide (Madagascar Dec 2013 = 70 deaths)
- As BWA, once infected, Soldiers are capable of spreading disease through coughing and bodily fluids. If left untreated for 24 hrs, aerosolized infections are invariably fatal.
- Vaccine prophylaxis is considered best protection since wearing PPE at time of covert attack is impractical
- Gentamicin used as an antibiotic, but must be started within first 24 hrs to avoid high mortality rates

Vaccine Manager: Dr. David Heath
Filovirus Vaccine

Potential ACAT II / TD Phase

**Program Description**

- MCS-JVAP will develop a trivalent vaccine system to protect against Ebola Sudan, Ebola Zaire and Marburg viruses. Program is developing competitive prototypes (VLP, VSV).
- **Contractors:** Battelle, Columbus, OH; TBRI, San Antonio, TX; Profectus Bioservices, Baltimore MD; USAMRIID
- **Contract Type:** CPFF / FPI / FFP
- **IOC/FOC:** 96 K / 350K TEDs* Draft CDD for Filo Vaccine Increment

*TED = Troop Equivalent Dose

**Recent Milestones or Events**

- Oct 14- awarded VLP contract to Fraunhofer for manufacturing efforts
- Feb 15- Fielded 50,000 GUP doses of VSVΔG to support Phase 2/3 trials in West Africa
- Mar 15- Fielded VSVΔG PEP vials to Walter Reed National Military Medical Center for High Risk Exposures
- 2QFY15 – Initiation of non-clinical duration studies

**Near Term Milestones or Events**

- 3QFY15- cGMP manufacturing of trivalent VSV N4CT1 candidate
- 4QFY15- Initiate first trivalent Phase 1 clinical trial (VSV N4CT1)

**Threat Overview**

- Presents a current threat beyond anything we’ve seen prior
- Former active Russian program to weaponize Marburg virus
- In 1992, Aum Shinrikyo attempted to obtain Ebola virus to make a bio-weapon from an outbreak in Zaire (DRC).
- Can be suitable for bio-weapon use because:
  - can be disseminated via aerosols
  - have a low infectious dose
  - cause high morbidity and mortality
  - cause fear and panic
  - now more readily available

**Unclassified**

Vaccine Manager: Ms. Rebecca Kurnat
**Program Description**

- MCS-JVAP is developing a new vaccine for the DoD intended to protect against aerosolized exposure to ricin toxin
- **Government Labs**: USAMRIID; WRAIR
- **Contractors**: University of Nebraska; Battelle, Columbus, OH
- **Contract Type**: FFP Tasks
- **IOC/FOC**: 290K/2.1M TEDs* Draft CDD for Ricin Vaccine (Dec 12)

*TED=Troop Equivalent Dose

**Recent Milestones or Events**

- JUL 13 – Funding removed in POM 15
- NOV 13 – Briefed DJPEO - continue to Phase 1b with government candidate (RVec™)
- MAR 14 – FDA acceptance of submitting intradermal clinical protocol for Phase 1b
- JAN 15 – GMP vaccine manufactured for Phase 1b/c
- FEB 15 – Ricin challenge stock well characterized, stable and large animal aerosol delivery system qualified

**Near Term Milestones or Events**

- 3QFY15 – Initiate Bulk Drug Substance technology transfer to the ADM
- 3QFY15 – Phase 1b Clinical Trial initiation
- 3QFY15 – Complete NHP (AG) LD50 and Natural History studies

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### Ricin Vaccine Schedule

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**Capabilities Documents**

- Draft CDD
- CDD

**Manufacturing Activities**

- GMP (Ph1)
- Technology Transfer to the ADM

**Testing**

- Phase 1A CT
- Phase 1B CT

**Threat Overview**

- Used in assassination attempts world-wide
- Ease of production and can distribute via mail
- Russia studied its use as a bioweapon
- Iraq was suspected to have experimented with “crude” unpurified ricin toxin
- Toxic by all routes of exposure, highly toxic via aerosol; resulting in epithelial necrosis w/in hrs of exposure, hemorrhagic edema and death w/in 24-72 hrs
- No effective therapy is available

**Vaccine Manager**: Mr. Chris Dorsey
Western, Eastern & Venezuelan Equine Encephalitis (WEVEE) Vaccine

Potential ACAT II / TD Phase

Program Description

- MCS-JVAP is developing a trivalent vaccine for DoD to protect against aerosolized exposure to three strains of alphaviruses; western, eastern and Venezuelan equine encephalitis viruses. Program is developing competitive prototypes.
- **Contractors:** NIAID, Bethesda, MD; Battelle, Columbus, OH
- **Contract Type:** IAA/FFP/CPIF
- **IOC/FOC:** 290K / 2.0M TEDs* Draft CDD for WEVEE Vaccine (Feb 13)

*TED = Troop Equivalent Dose

Recent Milestones or Events

- JAN 14 – Selected virus strains for NHP model
- JAN 14 – Completed in-life portion of VLP NHP challenge study
- MAR 14 – Completed cGMP BDS runs for VLP candidate
- MAR 15 - Pre-IND submitted or VLP/Initiate VRP work from Filo at CSU
- APR 15 - Purchased VRP Intellectual Property

Near Term Milestones or Events

- 3QFY15 – Submit strain selection to FDA
- 3QFY15- Award contracts for animal model efforts
- 3QFY15 – Initiate manufacturing process development of VRP vaccine candidate

Threat Overview

- The level of incapacitation, mortality, simplification of production and amenability of genetic manipulation have established WEE, EEE, and VEE viruses as high threat BWA.
- Easy to produce at high titers and have low infectious doses, highly infectious using aerosols, can be easily lyophilized (freeze dried) and stored for decades
- Estimated cost for supportive care associated with disease is approx $1M per patient
- Was weaponized in the past by both Russia and US

WEVEE Vaccine Schedule

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<td>VRP Ph 1 CT</td>
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</tbody>
</table>

Vaccine Manager: Mr. Andrew Glenn
Biological Prophylaxis Technology Needs (1 of 2)

• **Capability Gaps**
  – Rapid onset to protection (novel adjuvants)
  – Desire longer duration of protection
  – Stability of products at higher storage temperatures
  – Alternate routes of administration

• **Product Development Tools**
  – Animal model development
  – Natural history studies
  – Strain characterization and selection
  – Adjuvant development to support enhanced immunogenicity

• **In the S&T Pipeline for Transition Near Term (2016-21)**
  – Tularemia vaccine
  – Multi-Botulinum toxin vaccine (additional serotypes)
Biological Prophylaxis Technology Needs (2 of 2)

• S&T Push Efforts
  – New Generation Anthrax Vaccine
  – Q-Fever Vaccine
  – Melioidosis Glanders Vaccine
  – SEB Vaccine

• Far-Term Modernization Goals (FY21+)
  – Initiate development of prophylaxes to address the full range of biological hazards
  – Develop monoclonal antibodies to provide prophylaxis against weaponized infectious agents and toxins
MCS-JVAP wants to gather information regarding the use of Other Transaction Authority (OTA) consortium approach

- What incentives can we offer to entice Non-Traditional Defense vaccine developers to work with the DoD in an OTA consortium approach?
- What issues must be solved to develop a successful OTA consortium approach?
- Is there another approach that will provide a better solution?
Contact Us

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301-619-2156

MCS-Fort Belvoir  
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703-704-2374
Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Countermeasure Systems (MCS)-Chemical Defense Pharmaceuticals (CDP)

Autoinjector Portfolio Briefing

Presented at:
Other Transaction Authority Industry Day

Dr. David Smith
Deputy Joint Product Manager
Medical Countermeasure Systems
Chemical Defense Pharmaceuticals
david.j.smith222.civ@mail.mil

June 15, 2015
Mission

Provide the Warfighter and the Nation robust & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, radiological and nuclear threats
Product Overview
Chemical Defense Medical Products

Pre-Event

SNAPP
SOMAN NERVE AGENT PRETREATMENT PYRIDOSTIGMINE

BSCAV
BIOSCAVENGER

ATNA
ANTIDOTE TREATMENT NERVE AGENT AUTOINJECTOR

INATS
IMPROVED NERVE AGENT TREATMENT SYSTEM

CANA
CONVULSANT ANTIDOTE FOR NERVE AGENTS

AAS
ADVANCED ANTICONVULSANT SYSTEM

Post-Event
INATS Overview

• INATS is an enhanced treatment regimen against the effects of nerve agent poisoning
  – Development of an adjunct centrally-acting therapeutic for addition to the family of systems to increase survival against NTAs
    • Lead candidate - Scopolamine
  – Development of broad spectrum oxime to replace the currently fielded oxime (2-PAM)
    • Lead candidate - MMB4 DMS
  – Conduct of studies to generate data to support the use of the PB pretreatment against agents other than soman

• NTA-relevant product to replace and achieve the improved product performance over the currently fielded Antidote Treatment – Nerve Agent Autoinjector (ATNAA)
# INATS

## Current vs. Future

### Current State

<table>
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<th>Pre-Event</th>
<th>Nerve Agent Exposure</th>
<th>Post Event</th>
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<td>Pre-exposure</td>
<td>ATNAA (Self)</td>
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<td>Pre-exposure</td>
<td>ATNAA (Buddy)</td>
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<td>CANA (Buddy &amp; Medic)</td>
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</table>

- Soman Nerve Agent Pretreatment Pyridostigmine
- Pyridostigmine Bromide
- Antidote Treatment Nerve Agent Autoinjector
  - Atropine + Oxime (2-PAM)
- Convulsant Antidote for Nerve Agents
- Diazepam

### Interim State

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<td>AAS (Buddy &amp; Medic)</td>
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- Nerve Agent Pretreatment Pyridostigmine
- Additional Agents
- Antidote Treatment Nerve Agent Autoinjector
  - Atropine + Scopolamine + Oxime (2-PAM)
- Advanced Anticonvulsant System
  - Midazolam

### Future State

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- Nerve Agent Pretreatment Pyridostigmine
- Additional Nerve Agents
- Improved Nerve Agent Treatment Systems
  - Atropine + Centrally Acting Therapeutic + Broad Spectrum Oxime
- Advanced Anticonvulsant System
  - Midazolam

20150615 MCS Industry Day

UNCLASSIFIED
MCS-CDP wants to gather information regarding the use of Other Transaction Authority (OTA) consortium approach

– What incentives can we offer to entice Non-Traditional Defense developers to work with the DoD in an OTA consortium approach?
– What issues must be solved to develop a successful OTA consortium approach?
– Is there another approach that will provide a better solution?

How can we work with you? Ask questions?
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Medical Countermeasure Systems (MCS) Project Management Offices

<table>
<thead>
<tr>
<th>Office</th>
<th>Address</th>
<th>Phone</th>
<th>E-mail</th>
</tr>
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<tr>
<td>MCS-Fort Detrick (HQ)</td>
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<tr>
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Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Countermeasure Systems (MCS)-Biological Defense Therapeutics (BDTX)

Therapeutics Portfolio Briefing

Presented at:
Other Transaction Authority Industry Day

LTC Eric G. Midboe
Joint Product Manager
BioDefense Therapeutics (BDTX)
eric.g.midboe.mil@mail.mil

June 15, 2015
Overview

• Organizational Overview

• Biological Defense Therapeutics Mission

• Biological Defense Therapeutic Product Lines
BDTX
Organizational Structure

Joint Product Manager
Biological Defense Therapeutics (BDTX)
LTC Eric G. Midboe, Joint Product Manager
David Klaasse, Deputy Joint Product Manager

- HFV MCM
  - Mr. Adekunle Famodu

- EID Tx
  - Mr. Jay Wang

- CMDR-B
  - Mr. Adekunle Famodu (Acting)

- Toxin Tx
  - Mr. Steve Fernandez

Antiviral Therapeutics (TX)
- SNALP-G
  - Ebola

- Favipiravir
  - Influenza

- New Indications

Antibacterial TX

Anti-biotoxin TX

Hemorrhagic Fever Virus (HFV) Therapeutic
Emerging Infectious Disease (EID) Therapeutics
Countermeasures for Multi-Drug Resistance-Bacterial (CMDR-B)
Bio-Toxin Therapeutics
MCS-Biological Defense Therapeutics (MCS-BDTx)

**Mission**
Provide U.S. military forces and the nation safe, effective, innovative, and affordable therapeutic solutions to counter traditional, emerging and engineered biological threats.

**Vision**
A healthy and creative environment which inspires a talented team of professionals to rapidly develop innovative therapeutic solutions for dynamic biological threats.
• Therapeutics play a critical /strategic role in biological defense
  – Shield and sustain (prophylactic and treatment) against known viral, bacterial, and toxin BWAs including engineered or multi-drug resistant strains/variants

• The BDTX portfolio of therapeutics will enable Force Readiness and Sustainment
  – Broad spectrum anti-viral therapeutics will counter many threats with one drug
  – Broad spectrum anti-bacterial therapeutics will protect the warfighter from BWA that have been engineered for multi-drug resistance (MDR)
  – Platform based therapeutics will be targeted to respond to emerging or engineered strains/variants and may be approved with an EUA

Rapid treatment returns the force to duty
• Pipeline needs to be expanded to meet the requirements of the warfighter (BWA)
• S&T pipeline must continually be replenished with new compounds
Goal: To deliver a U.S. Food and Drug Administration (FDA)-approved, broad-spectrum medical countermeasure (MCM) to the Warfighter for protection against naturally occurring or biologically engineered viruses

Users: The Services, the nation, and allied forces

Future:
• FDA approval: FY16
• Favipiravir will be further developed to address other RNA viruses of concern to the DOD

Status:
• Contract awarded to MediVector, Inc. (Boston, MA) on 14 March 2012 to develop Favipiravir, a broad-spectrum MCM:
  – Efficacious against multiple strains of influenza, including the 2009 H1N1 virus, H7N9 virus and drug-resistant influenza strains;
  – Addresses a pronounced gap in the existing interagency viral MCM development portfolio
• Milestone B: 1Q FY13
• Phase 1 and Phase 2 clinical trials are complete
• End of Phase 2 (EOP2) meeting held in September 2013
• Phase 3 clinical trials: Initiated Dec 2013
**Goal:** Deliver FDA approved therapeutics targeting hemorrhagic fever viruses.  
– Current efforts are focused on RNA-directed platform technologies against Ebolavirus

**Users:** The Services, the nation, and allied forces

**Status:**
- Ebola MCM (FDA “fast track”) – Will Complete Phase 1 human clinical trials 1Q FY15
- 83% efficacious when administered within 2 days after exposure in non-human primates

**Future:**
- Milestone B: 4Q FY15
- Pilot animal efficacy studies: FY15
- Pivotal animal efficacy studies: FY16-17
- FDA approval: FY21 (Ebola MCM)
- Develop new drug candidates for other HFV indications

*Currently, there are no available vaccines or therapeutics to prevent or treat Ebola infections*
Goal:
Develop Medical Countermeasures (MCMs) for multi-drug resistant (MDR) bacteria, focusing on Biological Warfare Agents (BWAs) and organisms that are genetically modified to be MDR. The resulting product(s) will be US FDA-approved to prevent or minimize effects of MDR bacterial exposures.

Users: The Services and allied forces

Future:
• Milestone A: 1QFY15

Status:
• CMDR-B secured FY15-19 POM funding
• Market Survey and Request for Information completed
• Translational Teaming Charter with the Joint Science and Technology Office (JSTO) to support product development throughout entire RDT&E life cycle
• Exploring Translational Teaming opportunities outside the Chemical and Biological Defense Program (CBDP) including: US Army Medical Materiel Development Activity (USAMMDA); United States Army Medical Research Institute for Infectious Diseases (USAMRIID); Military Infectious Diseases Research Program (MIDRP); Critical Reagents Program (CRP); Advanced Development Manufacturing Capability (ADMC); Biomedical Advanced Research and Development Authority (BARDA)
Goal:
Develop post exposure prophylaxis (PEP) and treatment solutions to mitigate the detrimental effects caused by bio-toxins

Capability Status:
Currently the program is in Concept Development stage (Pre-MDD). The program is working with JSTO CBD to update Bio-Toxin Capability Transition Agreement (CTA) and identify mature technology for advanced development

Future:
• Pursue traditional product development and conduct a Materiel Development Decision (MDD) in FY15
• Seek a Milestone A Decision sometime in FY16
Discussion

• MCS-BDTX wants to gather information regarding the use of Other Transaction Authority (OTA) consortium approach
  – What *incentives can we offer* to entice Non-Traditional Defense *therapeutic developers* to work with the DoD in an OTA consortium approach?
  – What *issues must be solved* to develop a successful OTA consortium approach?
  – Is there *another approach* that will *provide a better solution*?

How can we work with you? Ask questions?
Contact Us

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