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
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June 15, 2015

MCS
MEDICAL COUNTERMEASURE SYSTEMS

Bottom Line Up Front

- **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?

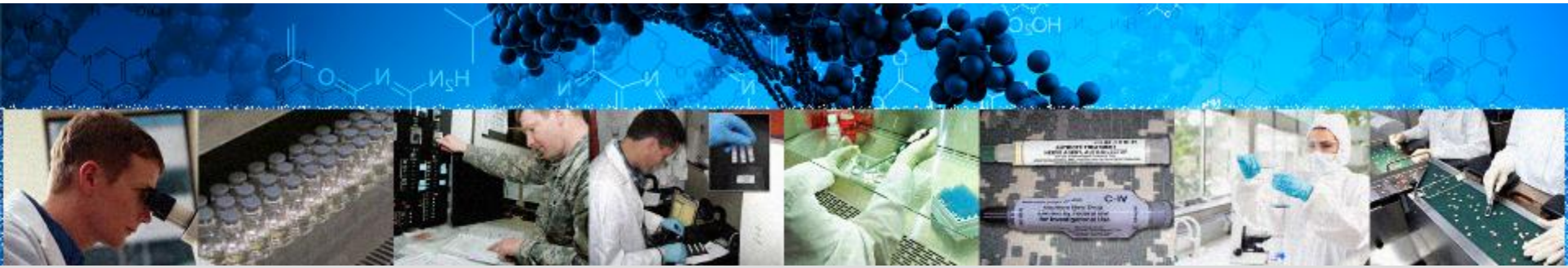
WHO WE ARE

MCS
MEDICAL COUNTERMEASURE SYSTEMS

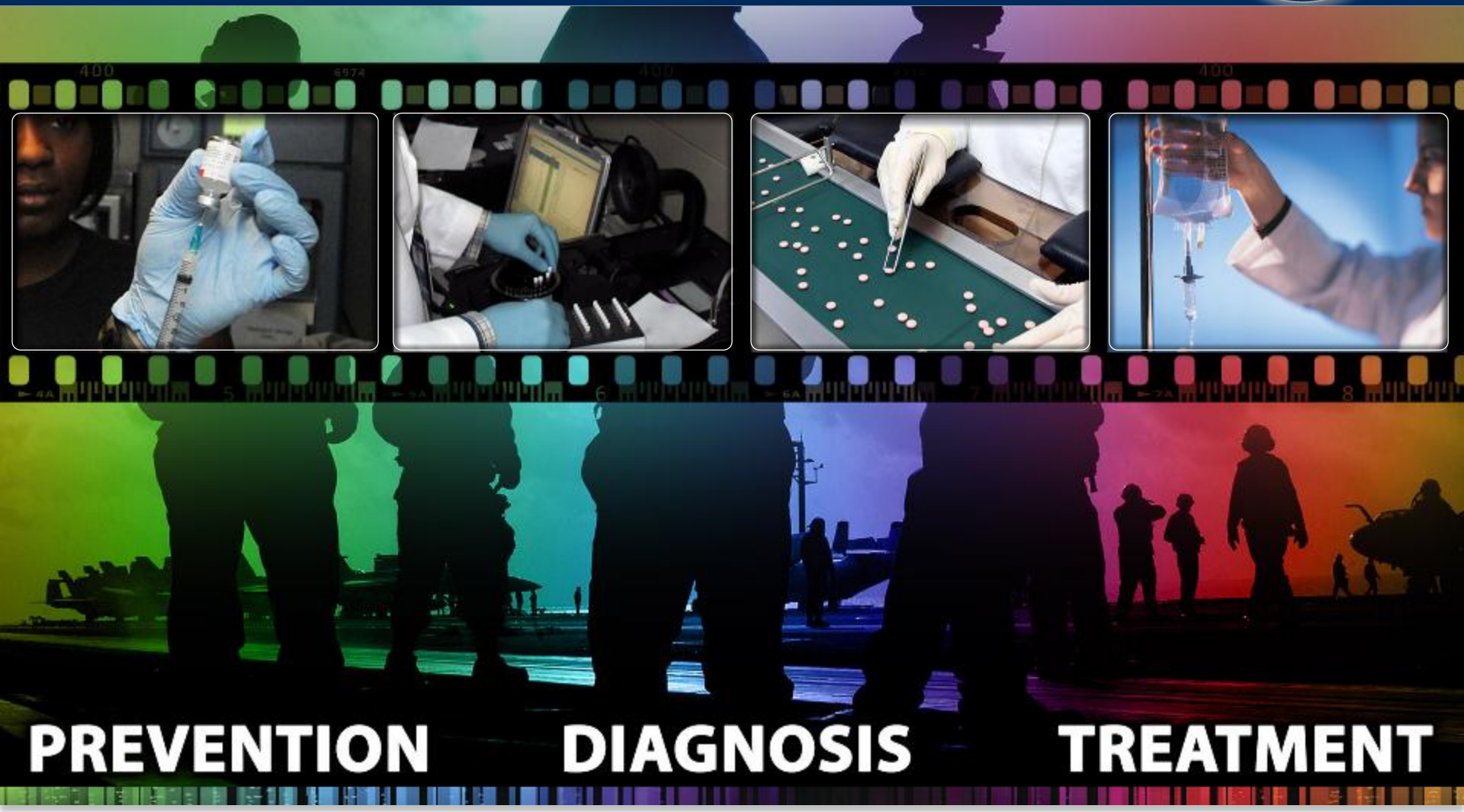
Medical Countermeasure Systems (MCS)

- **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)

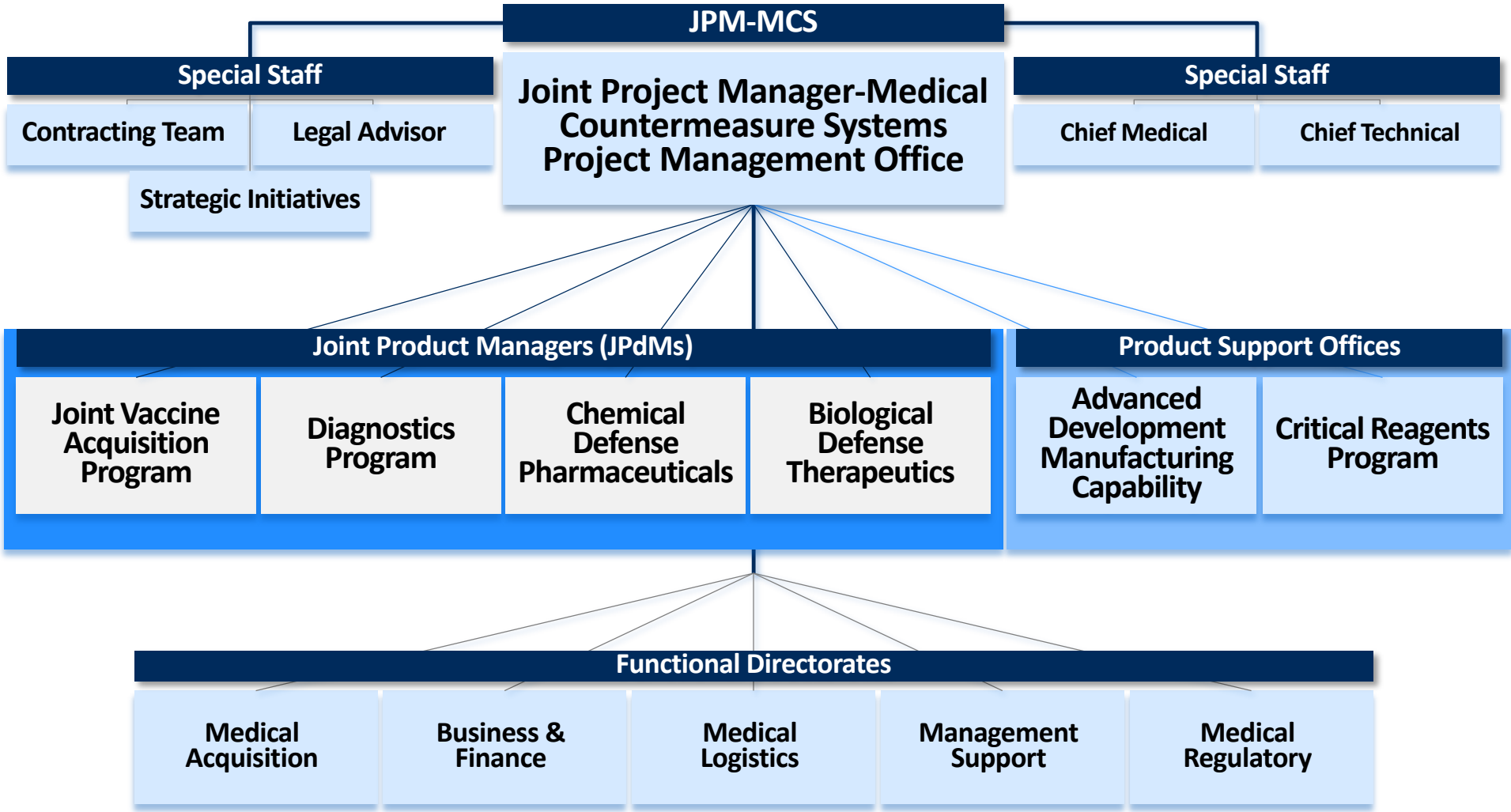


PROPHYLAXIS SUSTAINS THE FORCE

DIAGNOSTIC IDENTIFIES THREATS TO TREAT

THERAPEUTIC SAVES LIVES

MCS Organizational Structure



WHAT WE DO

Products in the Pipeline

LEGEND: PREVENTION | DIAGNOSTICS | THERAPEUTICS | DoD | FDA | ★= FDA Cleared

MDD | MS A | MS B | MS C (*LRIP*)

CAPABILITY	PRODUCT	IND	PHASE 1	PHASE 2	PHASE 3	BLA	NEXT MS	FDA LICENSURE
PREVENTION	Recombinant Botulinum A/B Vaccine						MS C 2017	2022
	Plague Vaccine						MS C 2015	2019
	Bioscavenger						MS C 2019	2020
	Filovirus Vaccine						MS B 2017	2025
	Ricin Vaccine						MS B TBD	TBD
	WEVEE Vaccine						MS B 2019	2029

MDD | MS A | MS B | MS C (*LRIP*)

	PRODUCT	DEV	PRE-CLINICAL	ANALYTICAL	CLINICAL	510K	NEXT MS	FDA CLEARED
DIAGNOSTICS	Next Generation Diagnostic System – Increment 1						MS C 2017	2017
	Next Generation Diagnostic System – Increment 2						MS B 2015	TBD
	JBAIDS Pre-EUA Kits: Typhus, Burkholdieria/Melioidosis						Pre-EUA	2014
	JBAIDS Food & Water Pathogens						2014	N/A

MDD | MS A | MS B | MS C (*LRIP*)

	PRODUCT	IND	PHASE 1	PHASE 2	PHASE 3	NDA	NEXT MS	FDA APPROVAL
THERAPEUTICS	Advanced Anticonvulsant System						FRP 2017	2017
	Emerging Infectious Disease (EID) Therapeutics – Flu						MS C 2016	2016
	Hemorrhagic Fever Virus (HFV) Therapeutic						MS B 2015	2021
	EID Therapeutics – New Indication						MS C 2021	2022
	Improved Nerve Agent Treatment System						MS B 2017	2021

As of Date: 01/09/15

MDD=Material Decision Document *MS=Milestone* *LRIP=Low Rate Initial Production* *FRP=Full Rate Production* *EUA=Emergency Use Authorization*

Products Fielded

LEGEND: PREVENTION DIAGNOSTICS THERAPEUTICS

NUMBER OF PRODUCTS DELIVERED

CAPABILITY	PRODUCT	FDA LICENSURE	FY02-12	FY13	FY14	TOTAL
PREVENTION	Anthrax Vaccine Adsorbed	2002	13.2 M	.66 M	.52 M	14.4 M
	Smallpox Vaccine	2007	4.5 M	.32 M	.21 M	5.0 M
	Vaccinia Immune Globulin	2005	288	240	0	528

CAPABILITY	PRODUCT	FDA CLEARANCE	FY02-12	FY13	FY14	TOTAL
DIAGNOSTICS	Joint Biological Agent Identification & Diagnostic System (JBAIDS)	2005	340	0	0	340
	JBAIDS Assay Kits	2005-11	22.8 K	2.29 K	1.30 K	26.4 K

CAPABILITY	PRODUCT	FDA APPROVAL	FY02-12	FY13	FY14	TOTAL
THERAPEUTICS	Antidote Treatment Nerve Agent Autoinjector (ATNAA)	2002	9.7 M	.28 M	0	9.9 M
	Convulsant Antidote Nerve Agents (CANA)	1990	5.2 M	.13 M	.02 M	5.3 M
	Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP)	2003	.49 M	.03 M	.01 M	.53 M

As of Date: 01/09/15

HOW WE DO IT

DoD: Meeting the Needs of the Warfighter

CAPABILITY DOCUMENTS

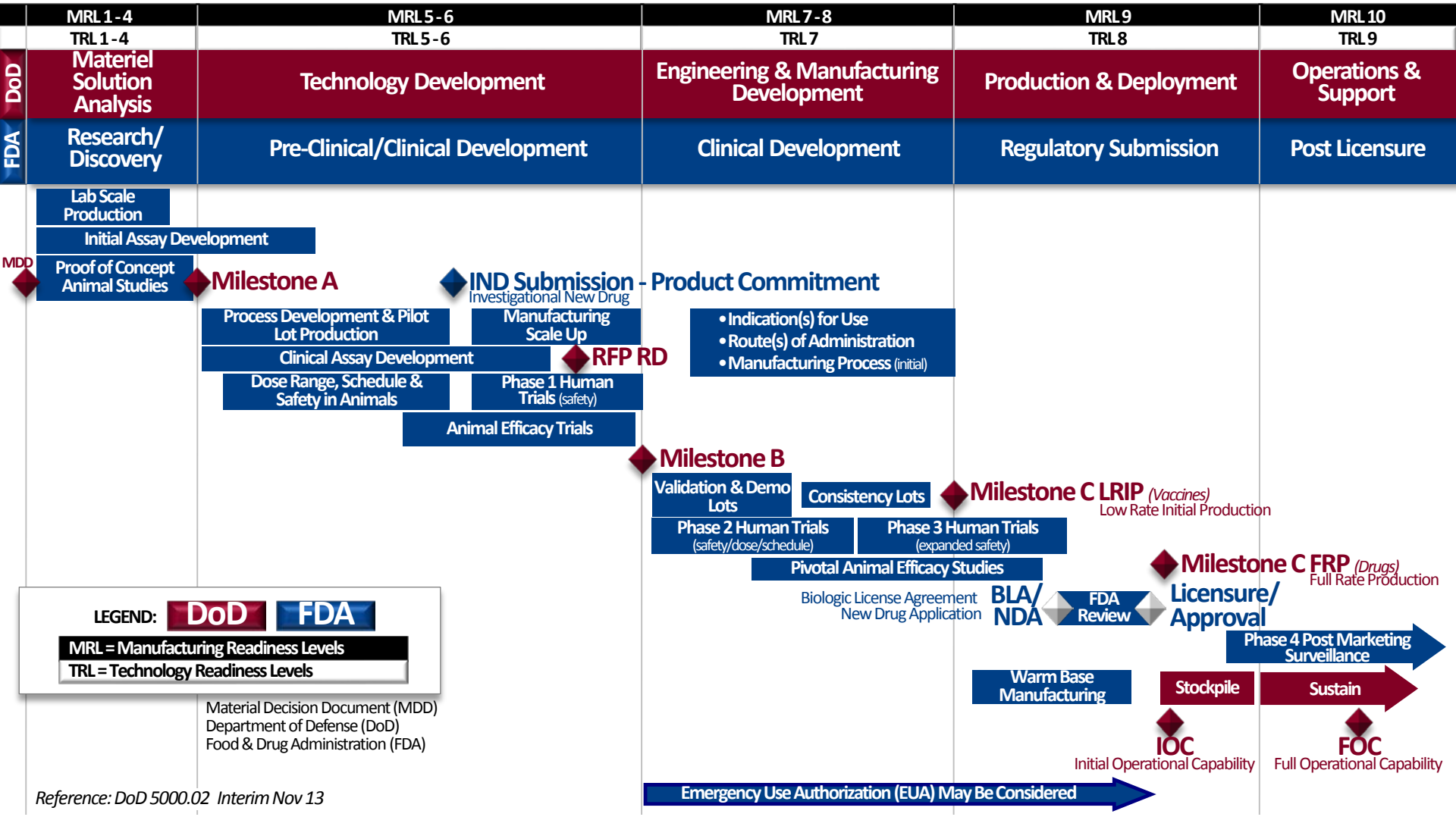
- Initial Capabilities Document (ICD)
- Capability Development Document (CDD)
- Capability Production Document (CPD)
- Key Performance Parameter = FDA Licensure

TRANSLATIONAL TEAMING

- Capability Technology Agreement (CTA)
- Technology Transition Agreement (TTA)

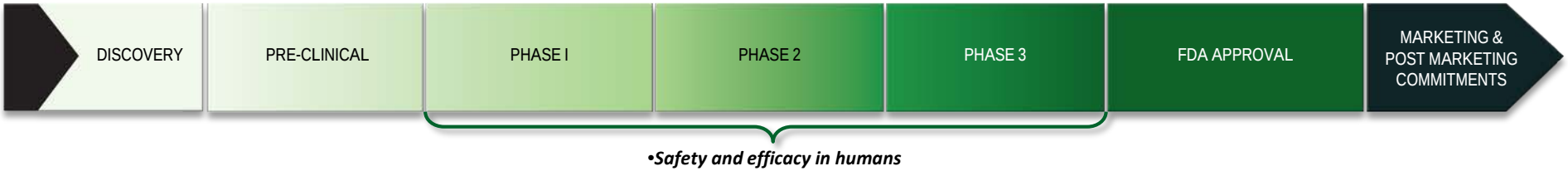
SAFE & EFFECTIVE FDA APPROVED PRODUCTS

Integration of the DoD and FDA Product Development Models

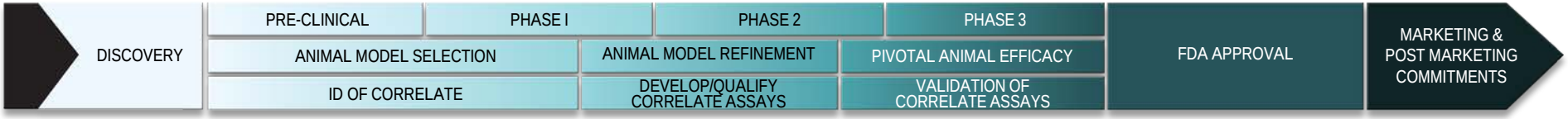


Product Development and the Animal Rule

TRADITIONAL LICENSURE PATHWAY



ANIMAL RULE LICENSURE PATHWAY



Animal Rule development requires integrated clinical and non-clinical programs

- **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

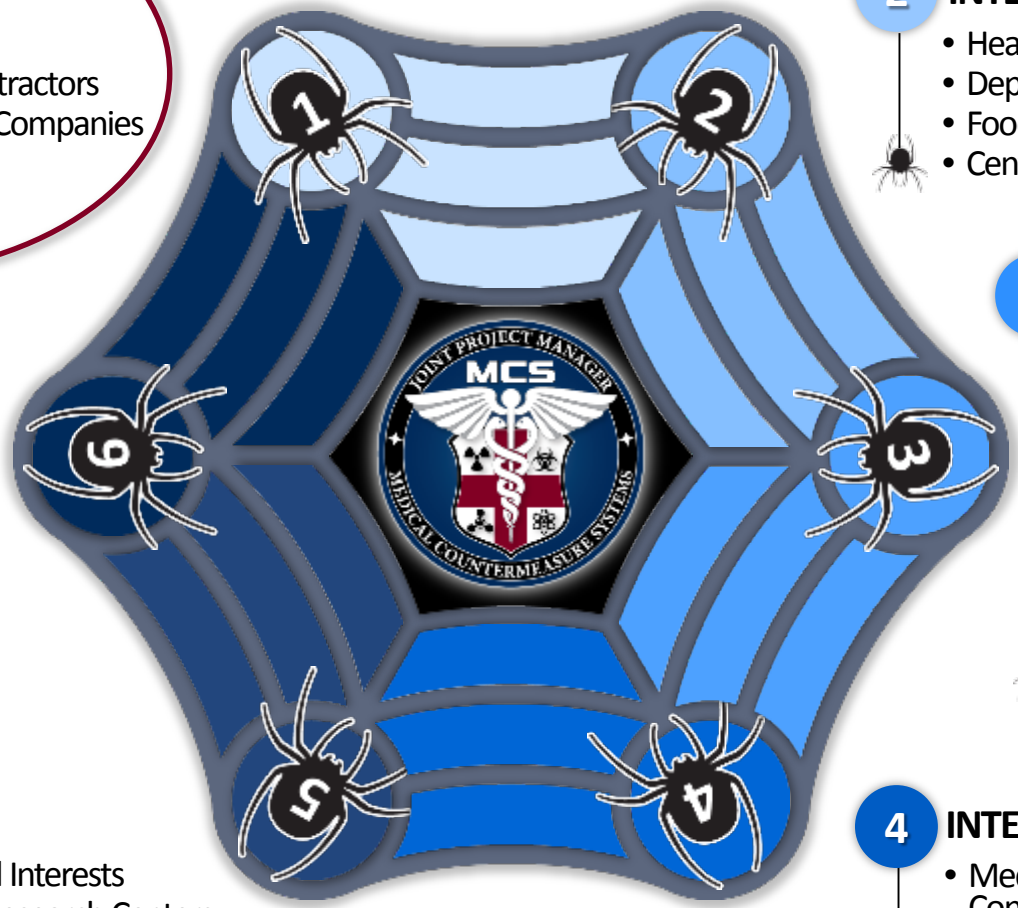
WHAT ARE WE DOING TO IMPROVE

MCS
MEDICAL COUNTERMEASURE SYSTEMS

Enhancing Stakeholder Partnerships

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

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



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

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

5 CONGRESS
- Congressional Special Interests
- University Affiliated Research Centers

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

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*?

How can we work with you? Ask questions?

Contact Us

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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)-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
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June 15, 2015

DIAGNOSTICS

MCS-Diagnostics

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

MCS-Diagnostics

Fielded/Development Products

FIELDED 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 / FDA	→**Next Acquisition MS:** MS C, FY16 →**Next Clinical MS:** 510(k) →**Projected FDA Clearance Date:** FY16

MCS-Diagnostics

Development Products / Business Opportunities

Next Generation Diagnostics System (NGDS) Increment 2	
Description	Common medical test equipment & diagnostic platform. Expand breadth of Inc 1 diagnostics capability to difficult pathogens, toxins, traditional Chemical Warfare Agents, non-traditional agents and radiation exposures
Last Milestone	Material Development Decision (MDD)
Clinical / FDA Accomplishment	▪ N/A
Next Steps DoD / FDA	→**Next Acquisition MS:** MS B FY16 →**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

MCS-Diagnostics

Advanced Development Products

Joint Hand-held Biological Identifier Increment 1		
Description	Provide the capability to rapidly and accurately identify bio-agents at the point of contact from environmental samples with a handheld device	
Last Milestone	MS B, Mar 2015	
Clinical / FDA Accomplishment	▪ NA	
Next Steps DoD FDA	→**Next Acquisition MS:** MS C, FY16 →**Next Clinical MS:** N/A; environmental identifier →**Projected FDA Clearance Date:** NA	

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

Milestone = MS

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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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)-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)
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June 15, 2015

JOINT VACCINE ACQUISITION PROGRAM

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

LEGEND: PREVENTION | DoD | FDA | ★= FDA Cleared

CAPABILITY	PRODUCT	FDA LICENSURE	FY02-12	FY13	FY14	TOTAL
PREVENTION	Anthrax Vaccine Adsorbed	2002	13.2 M	.66 M	.39 M	14.3 M
	Smallpox Vaccine	2007	4.5 M	.32 M	.17 M	5.0 M
	Vaccinia Immune Globulin	2005	288	240	0*	528

CAPABILITY	PRODUCT	MDD	IND	MS A	PHASE 1	MS B	PHASE 2	PHASE 3	BLA	MS C (*LRIP*)	NEXT MS	FDA LICENSURE
PREVENTION	Recombinant Botulinum A/B Vaccine		Jun 2004		Jan 2009		Nov 2011	2020	2021		MS C 2018	2022
	Plague Vaccine		Oct 2004		Jun 2007		Nov 2012	2019	2019		MS C 2020	2020
	Filovirus Vaccine		2016		2017		2020	2023	2024		MS B 2017	2025
	Ricin Vaccine		Jan 2014		2016		TBD	TBD	TBD		MS B TBD	TBD
	WEVEE Vaccine		2017		2019		2024	2027	2028		MS B 2019	2029

As of Date: 06/08/15

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

Botulinum A/B Vaccine
(rBV A/B)

ACAT II / E&MD Phase

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; Jublilant, 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*

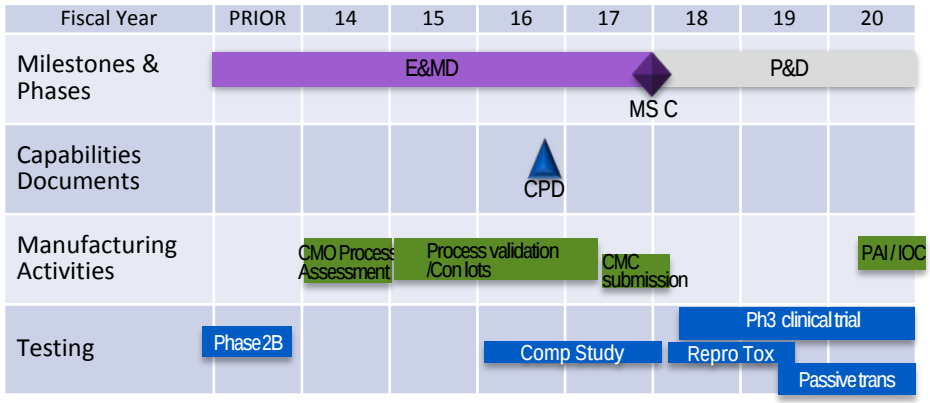
Recent Milestones or Events

- 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

rBOT Vaccine Schedule



Threat Overview

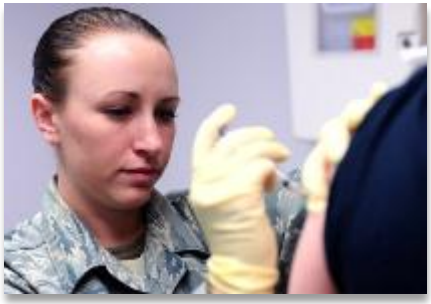
- One of the most lethal nerve toxins known (50-100 times more toxic than sodium cyanide)
- Estimated 1 gram of crystalline toxin, evenly dispersed and inhaled, has potential to kill 1.5M people
- Treatment without vaccination requires enormous demands on intensive medical care
- Historical use as BWA 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

ACAT II / E&MD Phase

Program Description



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

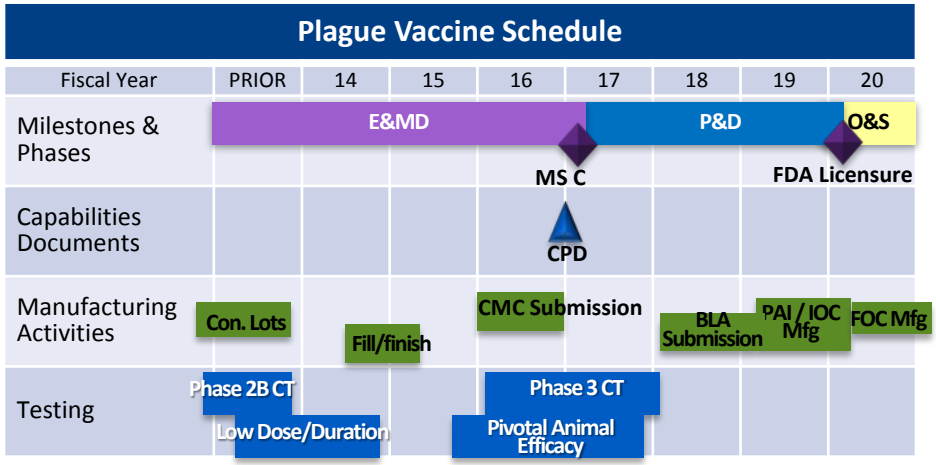
**TED=Troop Equivalent Dose*

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)

Filovirus Vaccine Schedule

Fiscal Year	PRIOR	14	15	16	17	18	19	20
Milestones & Phases	TD				MS B	E&MD		
Capabilities Documents				CDD				
Manufacturing Activities		Pilot Scale / GMP (Ph1)			Large Scale Process Development			
Testing	Animal Efficacy / Immunogenicity	Animal Dosing / Toxicity		Phase 1 CT				

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

Vaccine Manager: Ms. Rebecca Kurnat

Ricin Vaccine

Potential ACAT II / TD Phase

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*

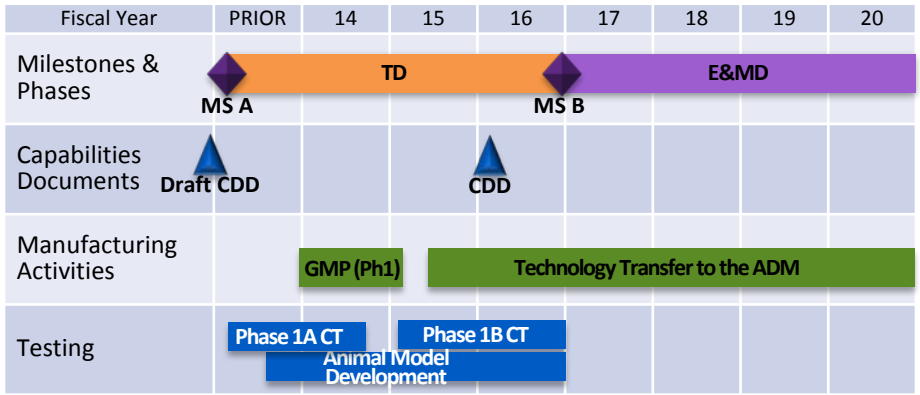
Recent Milestones or Events

- JUL 13 – Funding removed in POM 15
- NOV 13 – Briefed DJPEO - continue to Phase 1b with government candidate (RV*Ec*™)
- 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

Ricin Vaccine Schedule



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 epitheilial 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, Colombus, 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

WEVEE Vaccine Schedule

Fiscal Year	PRIOR	14	15	16	17	18	19	20
Milestones & Phases	TD						E&MD (MS B)	
Capabilities Documents	Draft CDD					CDD		
Manufacturing Activities		VLP GMP Mfg		VRP GMP Mfg				
Testing	VLP Pilot Animal Efficacy; VRP Confirmation			VLP Ph 1 CT; VRP Pilot NHP		VRP Ph 1 CT		

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

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

Discussion

- **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*?

How can we work with you? Ask questions?

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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)-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

CHEMICAL DEFENSE PHARMACEUTICALS

MCS-Chemical Defense Pharmaceuticals (MCS-CDP)

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

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

Pre-Event	Nerve Agent Exposure	Post Event		
SNAPP		**ATNAA** *(Self)*	**ATNAA** *(Buddy)*	**CANA** *(Buddy & Medic)*
Soman Nerve Agent Pretreatment Pyridostigmine ***Pyridostigmine Bromide***		Antidote Treatment Nerve Agent Autoinjector ***Atropine + Oxime (2-PAM)***		Convulsant Antidote for Nerve Agents ***Diazepam***
pre-exposure		treats symptoms of nerve agents		seizures

Interim State

Pre-Event	Nerve Agent Exposure	Post Event		
SNAPP		**ATNAA** *(Self)*	**ATNAA** *(Buddy)*	**AAS** *(Buddy & Medic)*
Nerve Agent Pretreatment Pyridostigmine ***Additional Agents***		Antidote Treatment Nerve Agent Autoinjector ***Atropine + Scopolamine + Oxime (2-PAM)***		Advanced Anticonvulsant System ***Midazolam***
pre-exposure		treats symptoms of nerve agents with enhanced survival		seizures

Future State

Pre-Event	Nerve Agent Exposure	Post Event		
SNAPP		**INATS** *(Self)*	**INATS** *(Buddy)*	**AAS** *(Buddy & Medic)*
Nerve Agent Pretreatment Pyridostigmine ***Additional Nerve Agents***		Improved Nerve Agent Treatment Systems ***Atropine + Centrally Acting Therapeutic + Broad Spectrum Oxime***		Advanced Anticonvulsant System ***Midazolam***
pre-exposure		treats symptoms of nerve agents with enhanced survival		seizures

Discussion

- **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)-Biological Defense Therapeutics (BDTX)

Therapeutics Portfolio Briefing

Presented at:

Other Transaction Authority Industry Day

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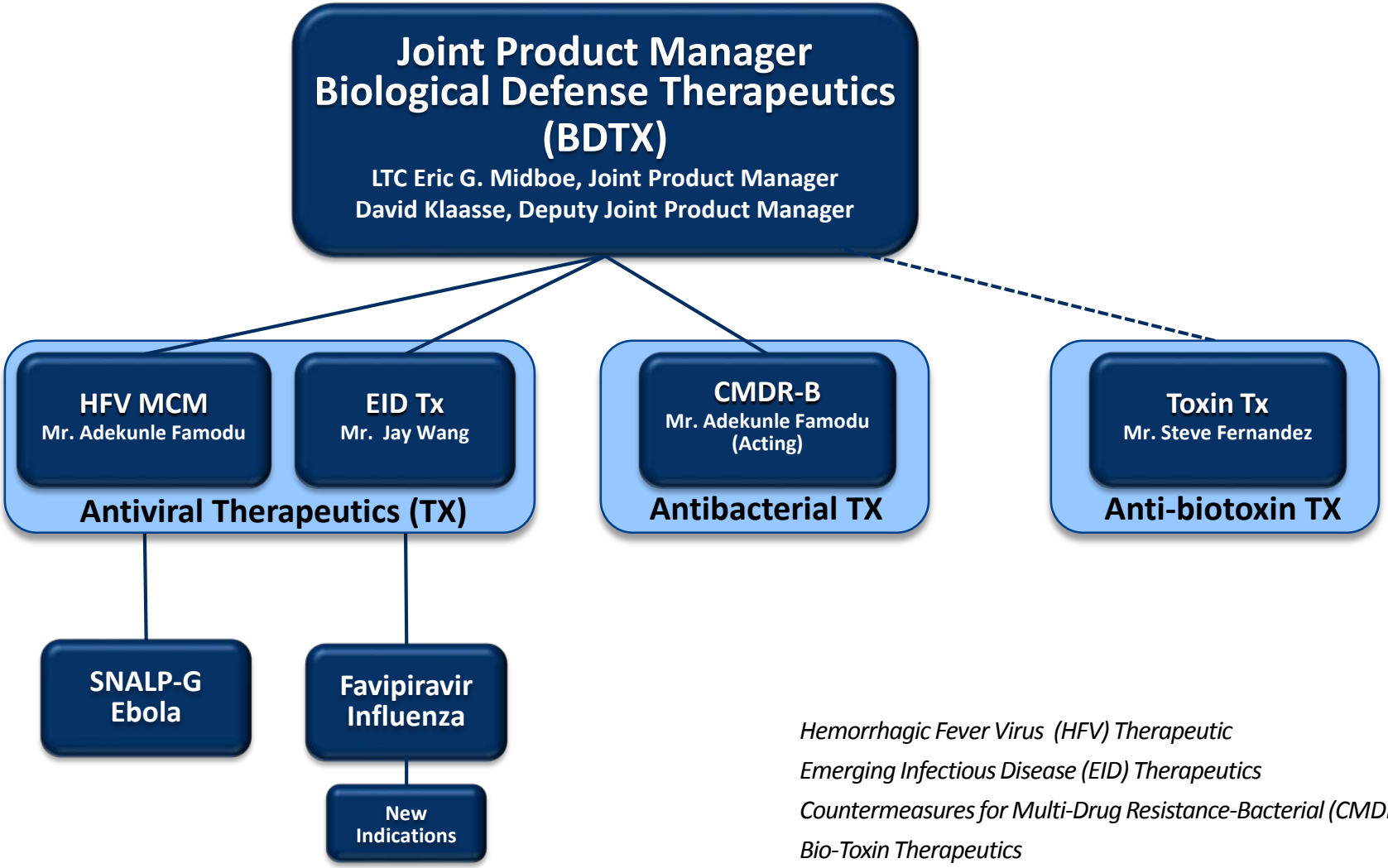
June 15, 2015

BIOLOGICAL DEFENSE THERAPEUTICS

Overview

- Organizational Overview
- Biological Defense Therapeutics Mission
- Biological Defense Therapeutic Product Lines

BDTX Organizational Structure



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.

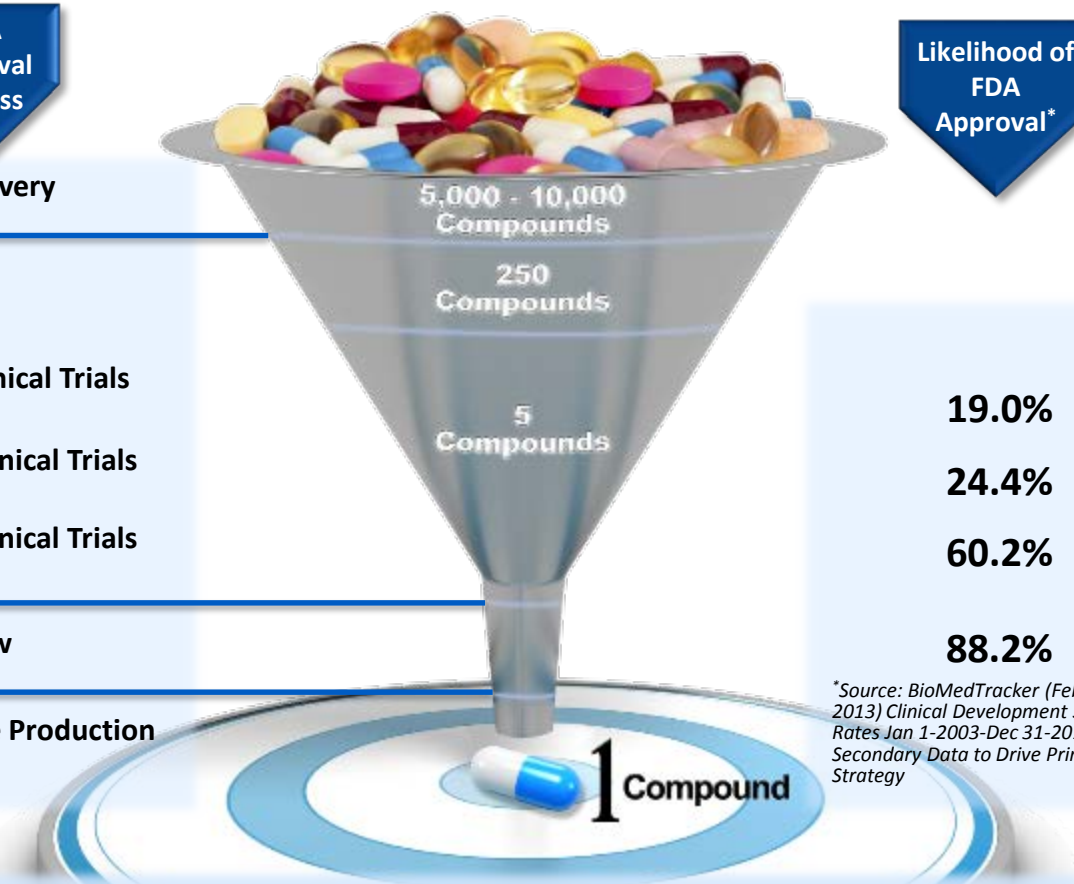
BDTX
Importance of Therapeutics

- **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

BDTX Medical Countermeasure Development

DoD Acquisition Process	FDA Approval Process	Likelihood of FDA Approval*
Material Solution Analysis Phase	Drug Discovery	
Technology Maturation & Risk Reduction Phase	Pre Clinical	
	Phase I Clinical Trials	19.0%
Engineering & Manufacturing Development Phase	Phase 2 Clinical Trials	24.4%
	Phase 3 Clinical Trials	60.2%
Production Decision	FDA Review	88.2%
Production & Deployment Phase	Large Scale Production	



*Source: BioMedTracker (February 2013) Clinical Development Success Rates Jan 1-2003-Dec 31-2012. Uses of Secondary Data to Drive Primary Strategy

- **Pipeline needs to be expanded to meet the requirements of the warfighter (BWA)**
- **S&T pipeline must continually be replenished with new compounds**

Emerging Infectious Disease (EID) Tx Overview

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

Hemorrhagic Fever Virus (HFV) MCM Overview

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

Currently, there are no available vaccines or therapeutics to prevent or treat Ebola infections

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

Countermeasures for Multi-Drug Resistance-Bacterial (CMDR-B) Overview

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)

Bio-Toxin Therapeutics Overview

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**
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How can we work with you? Ask questions?

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