



# Joint Project Manager Transformational Medical Technologies Advanced Planning Briefing for Industry

September 7, 2011

*“Protecting the Warfighter and the Nation from Biothreats.”*



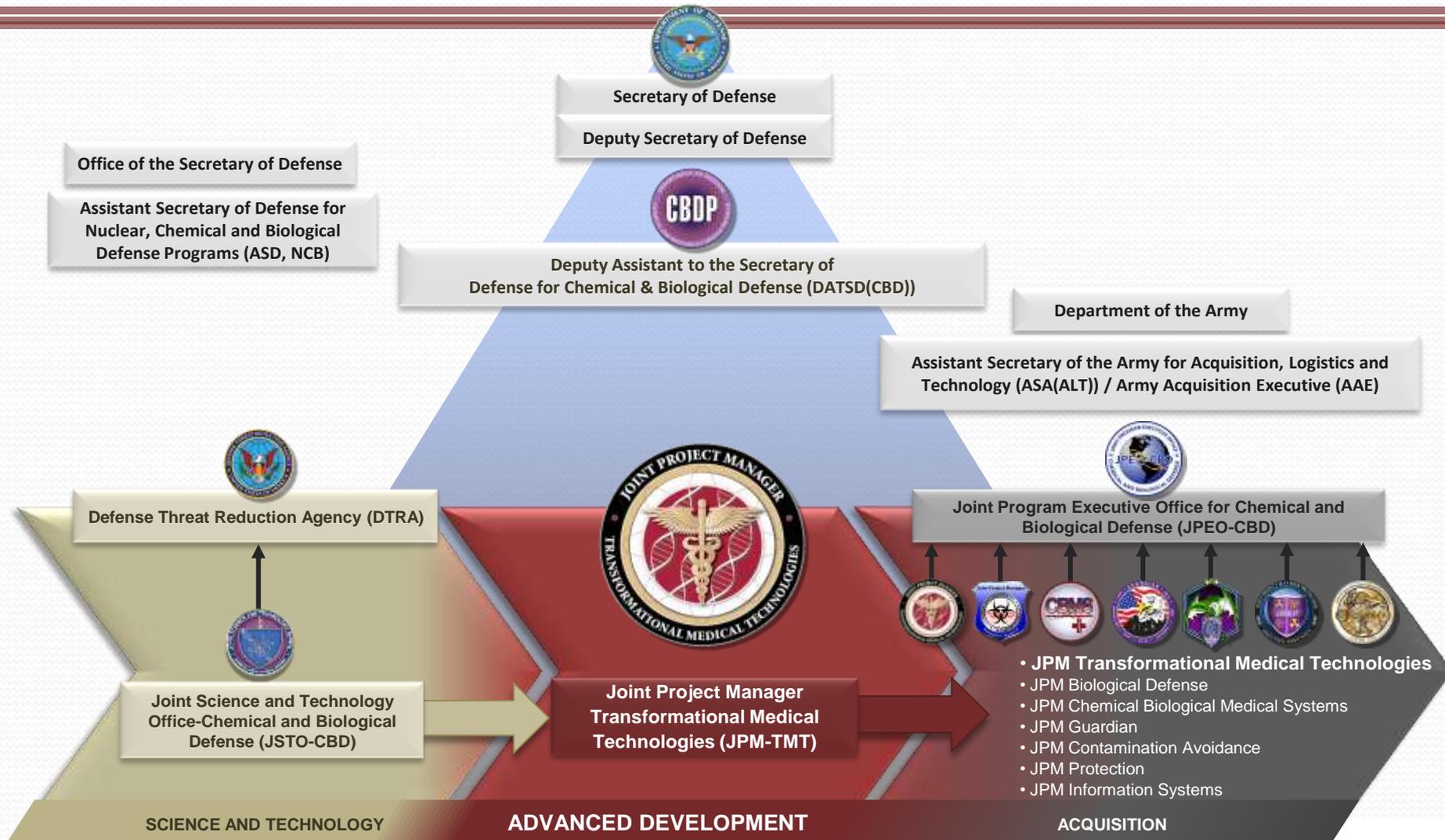
**MR. DAVID E. HOUGH**  
*Joint Project Manager, TMT*



## **JPM-TMT MISSION:**

*Provide the Warfighter and the nation with biosurveillance response capabilities and medical countermeasures to protect against emerging, genetically engineered or unknown biothreats.*

# JPM-TMT Organization



# JPM-TMT: A Vital Component to the Integrated National Biodefense Portfolio



## JPM-TMT

Broad spectrum solutions to the *unknown* biological threat and *emerging* infectious disease

- Broad-spectrum antivirals
- Broad-spectrum antibiotics
- Host-targeted therapeutics

## NATIONAL BIODEFENSE PORTFOLIO

### DoD-Unique

Prophylaxis (Vx) and Therapeutic (Rx):

- SEB
- Tularemia
- Hemorrhagic fevers
- Ricin
- Shigellosis
- Viral encephalopathies

Prophylaxis (Vx):

- Brucellosis
- Cholera
- Glanders
- Plague
- Q Fever
- Botulism
- Tularemia
- Typhus
- T2 mycotoxin



### Common to DoD and HHS



Therapeutic:

- Tularemia
- Botulism
- Junin
- Influenza

Prophylaxis and Therapeutic:

- Anthrax
- Hemorrhagic fevers
- Smallpox

### HHS-Unique

- Burkholderia sp. Rx
- Plague Rx
- Smallpox Vx for special populations



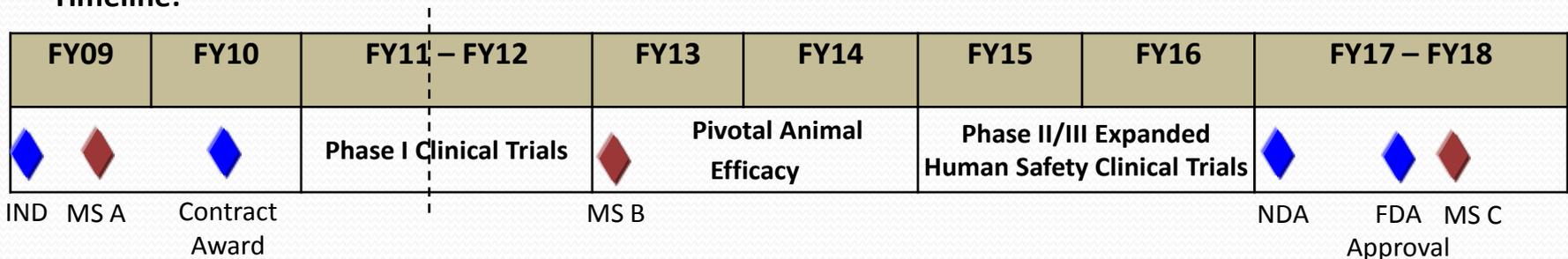


# JPM Viral Countermeasure Acquisition Program



**Program Objective:** Acquire an FDA-approved viral medical countermeasures (MCM) that is based on an adaptable platform technology to minimize the effects of Ebola and Marburg virus infection.

**Timeline:**



**Current Effort:**

- Phase 1 Clinical Trials in progress for Ebola and Marburg MCM

**Follow-on Efforts:**

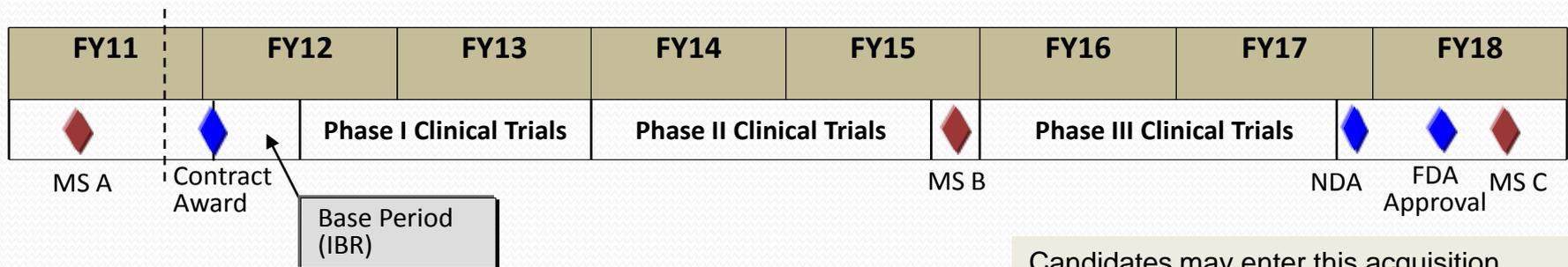
- Develop host immune enhancement viral countermeasure (FY 14 Initiation)
- Leverage platform technology against other Hemorrhagic Fever Viruses (HFV) in anticipation of HFV-like engineered biowarfare agents (BWA) (FY 17 Initiation )

# JPM Emerging Infectious Diseases (EID) Countermeasure Acquisition Program



**Program Objective:** Acquire an FDA-approved EID MCM that is based on a rapidly adaptable platform technology and/or possess broad-spectrum efficacy against influenza, specifically including the H1N1 virus.

## Timeline:



Candidates may enter this acquisition later in the lifecycle according to their level of maturity.

## Current Effort:

- Source selection ongoing

## Follow-on Efforts:

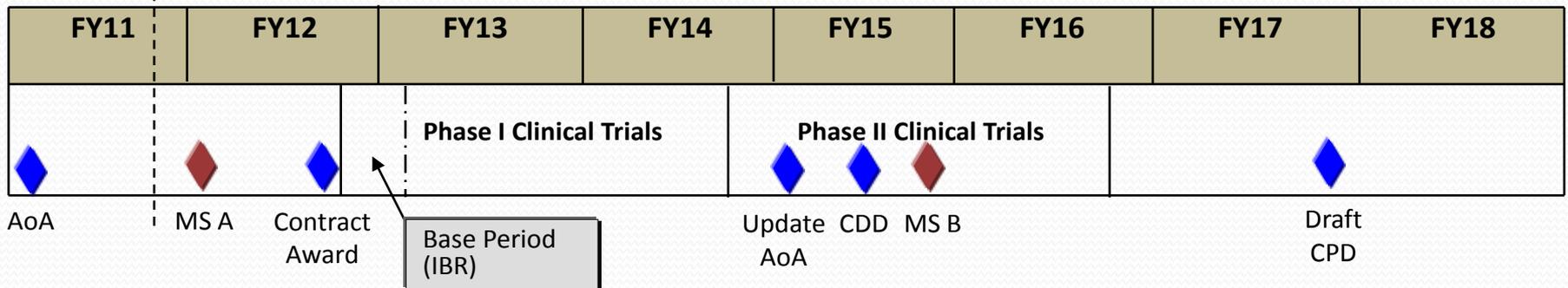
- Conduct an AoA at MS B to determine if new MCMs exist in the market place for potential inclusion in the EID program.
- Continue coordination with JSTO and industry for development of products for transition to advanced development for emerging infectious diseases.

# JPM Bacterial Countermeasure Acquisition Program



**Program Objective:** Obtain an FDA-approved broad-spectrum bacterial countermeasure (BS BCM) to combat the effects of bacterial infections and fill existing capability gaps to protect the Warfighter and the nation against biothreats.

## Timeline:



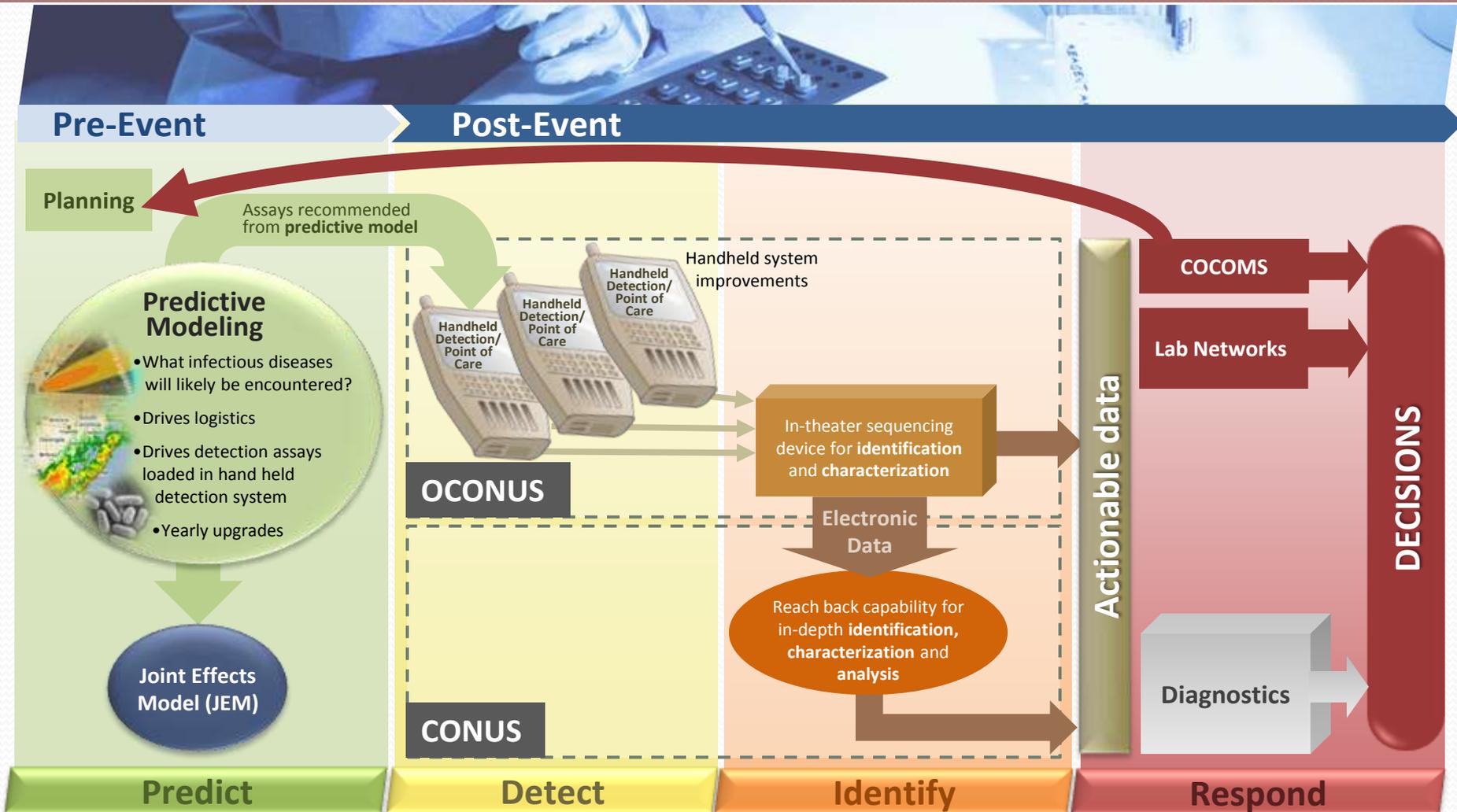
### Current Effort:

- Preparing for MS A review 1Q FY12.

### Follow-on Effort:

- Update AoA prior to MS B to determine if new MCM exist for inclusion in the program.

# JPM-TMT Biosurveillance & Response System



# JPM Biosurveillance & Response System Program



**Program Objective:** Integrate complimentary technologies to develop systems that predict, detect, identify and respond to emerging infectious diseases and novel biothreats.

## Timeline:

FY12	FY13	FY14	FY15	FY16	FY17	FY18	Beyond the POM
Prototype System Development ♦	Limited Objective Exercise ♦	COCOM Sponsored Exercise ♦	Field Increment 1		Field Increment 2		
MDD	MS A	MS B	MS C				

## Current Efforts:

- Continue coordination with biological health and defense enterprise for the development of products that can be integrated into the biosurveillance and response system to counter emerging infectious diseases.
- Continue system improvement to increase system capabilities and reduce response time.

JPM-TMT programs are structured to ensure medical countermeasure (MCM) products and systems are **successfully developed and fielded to the Warfighter.**



create  
collaborate  
communicate



# CBA APBI BRIEFING

DEFENSE THREAT REDUCTION AGENCY

JOINT SCIENCE AND TECHNOLOGY OFFICE

CHEMICAL BIOLOGICAL DEFENSE

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# WHAT GUIDANCE IS DIFFERENT?

- **Presidential and OSD / CBDP Guidance**, including:

***“We are launching a new initiative that will give us the capacity to respond faster and more effectively to bioterrorism or an infectious disease – a plan that will counter threats at home and strengthen public health abroad”***

**President Barack Obama**

*State of the Union Address on January 27, 2010*

***“Infectious diseases – either emerging or reemerging – must be a focus of the Department...”***

**Mr. Andy Weber**

*CBDP FY 2012-2017 Program Strategy Guidance*



# A CLOSER LOOK: BIOSURVEILLANCE AND DIAGNOSTICS

Center for Global Health and Security  
Communicate

## Enablers

Novel Threat Research

Applied Math Tools

Multifunctional Materials

Flexible Design Manufacturing

Systems Biology

## Strategic Thrusts

Disease Surveillance, Threat Detection, and Point of Need Diagnostics

Threat Activity Sensing and Reporting

Adaptive Medical Countermeasures and Technologies

Rapid Response and Restoration Science and Technology

## Products In Development

- **Highly multiplexed/parallel Direct Air Identification**
- **Presymptomatic diagnostics devices**
- **Field sequencing**
- **Geospatial COP**
- **Predictive genomics**
- **Computational Biosurveillance Info Mgt**

## Primary Approach

**Rqmts Pull**

**Rqmts Pull**

**Balanced**

**Balanced**

**Tech Push**

**Tech Push**





# Disease Surveillance and Future Diagnostics

## CBRN

### AGENT/HOST TARGET IDENTIFICATION

### ENABLING CAPABILITIES

Antibiotic Resistance Markers

Pre-symptomatic Biomarkers

Host Biomarkers

Pathogen ID

Bioinformatics

High Content Data Backbone

- Pathogen Sequences
- Host-Agent Dynamics Signatures
- Characterized Reagents

Diagnostic and Disease Targets

Both Core Medical and TMT Contributions

Sample Prep & Preserve

Platform Technologies

Engineering/Performance Drivers

Future Systems Development

- Enabled by informatics and device innovations
- Configurable for emerging threats

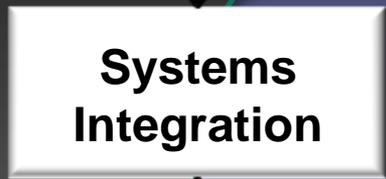
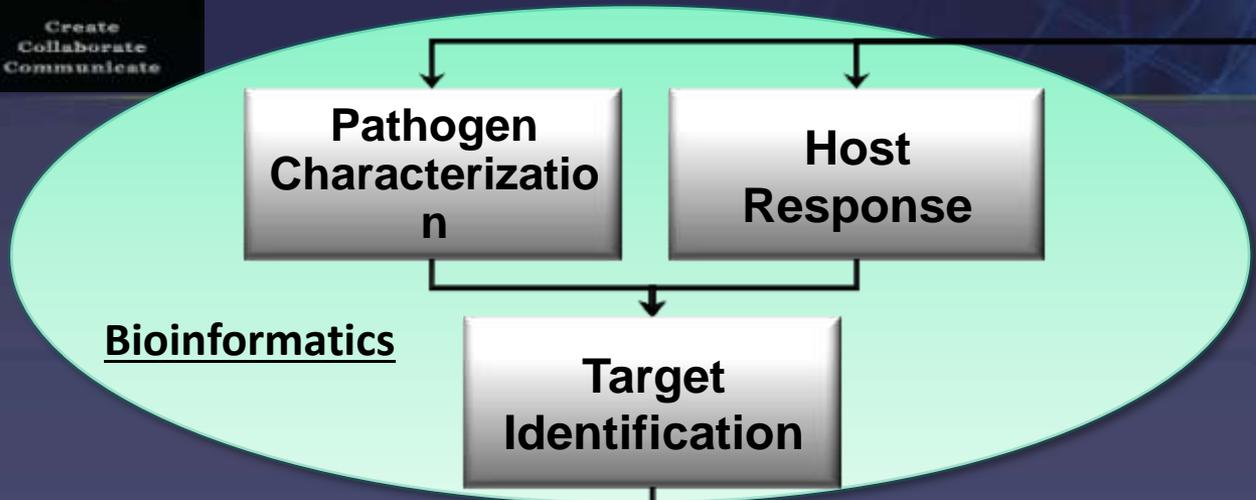


# Diagnostics and Disease Surveillance Division



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- Biomarker Discovery
- Systems Development
- Translational Diagnostics



**FDA Clearance**

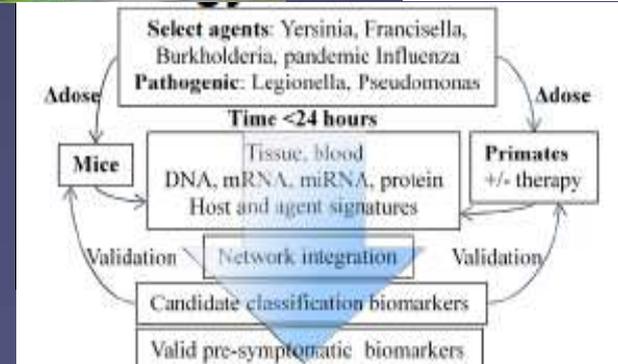
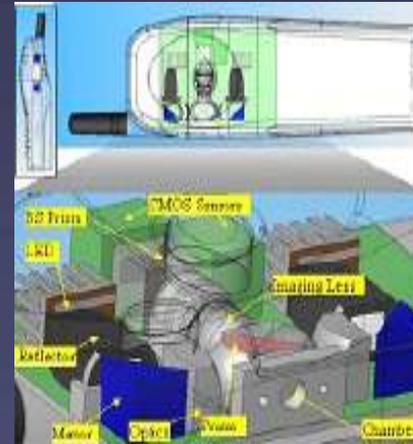
**No FDA Clearance**





# Medical Diagnostics: Focus and Top-line Investments

- Providing high quality data closer to the point of need
- This area comprises:
  - Device innovation
  - Panels of biomarkers driven by bioinformatics
  - Epidemiological modeling tools
- Translational product development



## Endstate

- Recombinant antigen characterization pipeline delivered by FY12
- Minimum of two NGDS increment 2 candidate prototypes by FY15
- Verified panel of host biomarkers by FY15
- Decision support system incrementally delivered until FY17

# Strategic Enhancements of Diagnostic and Medical Surveillance capabilities

- **Biomarker strategy:**

- **Current:** Support NGDS increment 1 to discover, develop, and verify full menu of class and agent-specific biomarker panels not addressed by the present CRP panels (eg. CCHF, RVFV)
  - Focused on proof-of principle for *host-based biomarkers*, world-class performers, sepsis model for clinical utility
- **Future:** Support NGDS increment 2 with a broad development pipeline for host response (and agent) diagnostic targets enabled by an integrated bio-informatic backbone
  - Existing and emerging threat agent early diagnostic biomarkers through BM validation in clinical proxy animal models





# Medical Diagnostics: Milestones

**Near Term**  
**1-2 Years**

**Mid Term**  
**3-5 Years**

**Far Term**  
**5-10+ Years**

Agent characterization pipeline (Supports CALS/Field Analytics/NGDS Inc. 1)

## Diagnostic Assay Development

Verified panels of biomarkers to support assay development for deployable diagnostic / detection systems and FDA approval

**Diagnostic Point of Need Device (s)**  
NGDS increment 2 candidate prototypes

**Biosurveillance tools Disease Surveillance tools**

NGDS increment 2 candidate prototypes

## Decision Support System

Incremental delivery of decision support capability for biological and medical analysis needs

Projects



# Transitional Diagnostics Thrust

- Systems Integration (system performance verification)
  - Standardized analytical studies to verify sample processing and assay performance on diagnostic platforms
  - Standardized animal studies to verify sample processing and assay performance on diagnostic platforms
- Medical Diagnostics
  - Pre-EUA submissions (with Advanced Development)
  - Transition multiple candidates to advanced developers, other customers
  - Pandemic/Epidemic Response
- Disease Surveillance – To Inform Dx System/Assay Development
  - **Prediction of Epidemic/Pandemic/Genetic Engineering**
    - **Vector assessment**
    - **Zoonotic surveillance**
    - **Epidemiological modeling**
  - Collection characterization





# Strategic Enhancements of Diagnostic and Medical Surveillance capabilities

- **Device Platform Strategy:**
  - **Current:** Structured development process to support NGDS INC. 1 for significant device platform investment (consistent with Field Analytics ICD)
    - Established inter-governmental Technology Review Panel/ evaluation centers
    - Designed to enable NGDS INC. 1 to enter acquisition in FY13
  - **Future:** Significant investment in development of multiple platforms to support NGDS INC. 2 with:
    - Down-selection methodology compliant with FDA Design Control Process
    - Incrementally add capabilities and assays via spiral development process
    - Alignment with early tech. developers (DARPA, industry) and with CBMS
  - **FUTURE ACTIVITIES REQUIRE SIGNIFICANT ADDITIONAL INVESTMENT TO MEET NGDS SCHEDULE (Sp. INC. 2)**



# Strategic Enhancements of Diagnostic and Disease Surveillance capabilities

- **Disease Surveillance strategy :**

- **Current:** Leverage Epidemiological surveillance and modeling to drive identification of emerging pathogens
  - Focused on standard threat list and strain-specific molecular and immunoassay development
- **Future: Accrual,** characterization will lead to rapid/facile assay menu expansion and transition to advanced development

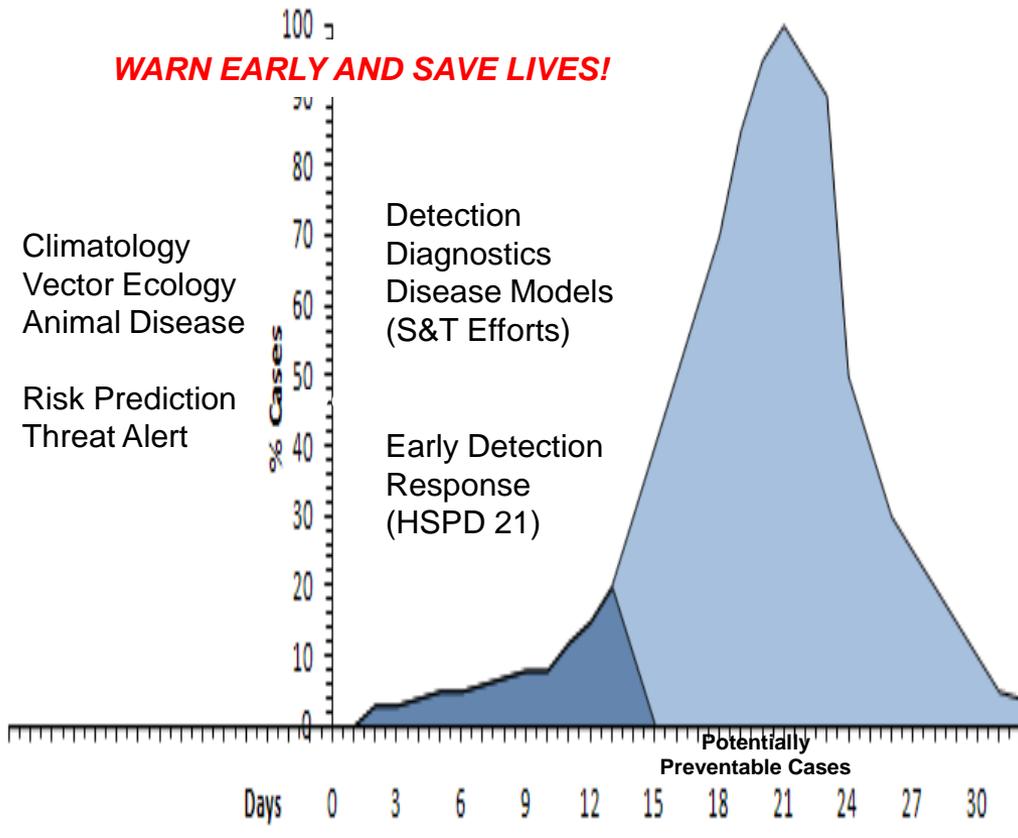


# Biosurveillance: Focus and Top-Line Investment

Create  
Collaborate  
Communicate



**WARN EARLY AND SAVE LIVES!**



## Biosurveillance Definition

“The term **“biosurveillance”** means the process of data-gathering with appropriate analysis and interpretation of biosphere data that might relate to disease activity and threats to human or animal health – whether infectious, toxic, metabolic, or otherwise, and regardless of intentional or natural origin – in order to achieve **early warning** of health threats, **early detection** of health events, and overall **situational awareness** of disease activity.” (HSPD-21)

## BSV Requirements/ Gaps

- Gaps identified in DoD to PPD-2 Implementation Plan for National Strategy for Countering Biological Threats: 2011 Edition\*
- Joint Requirements Office
- COCOM Requirements

\*Adapted from Draft PPD-2 Implementation Plan for National Strategy for Countering Biological Threats: 2011 Edition



# Biosurveillance: Milestones

Create  
Collaborate  
Communicate

## Near Term 1-2 Years

## Mid Term 3-5 Years

## Far Term 5-10+ Years

### Diagnostics / Sample Preparation

Matrix interference, Signature Erosion, Target a-priori, Antibiotic Resistance, Interoperable

### Characterize Agent

Phenotype, Genotype, Persistence

### Detection

Field Sequencing for environment and human, Mobile Sensors, Dynamic Materials, Interoperable, Regulatory standards for safety & cleanliness

### Future Diagnostic

Human Response Biomarkers amenable to FDA

### 'Omics / Bioinformatics Reference Data Sets/Regulatory Science

Toxicokinetics/MCM design/Development/Manufacturing

### Computational Biosurveillance Information Management

Fusion & Analysis / Archival & Retrieval / Data Standards  
Determine most beneficial sources of data for surveillance and early warning

### Geospatial COP

Convert boundaries and population dynamics into disease recognition

### Ecosystem Studies / Disease Baseline

Identify populations at risk for epidemics due to climate events or other ecological changes that alter the dynamics of microbes, their environment or animal reservoirs and disease vectors

### Predictive Genomics

Environmental Species Jump: Understand Vector/Animal/Human Interface, Research microbial host-receptor interaction and determinants of pathogenesis

### M&S / Statistical Prediction / Early Warning Algorithms

Disease propagation, Human habituation, Medical resource consumption

Projects



# JPM-TMT Innovations and Successes



Innovations	Successes
Successful completion of <b><u>rapid-response integration exercises</u></b>	<ul style="list-style-type: none"> <li>• Bacterial and viral threats (18 days)</li> <li>• Dengue virus (11 days)</li> <li>• H1N1 pandemic (7 days)</li> </ul>
First U.S. government agency to invest in advanced development of promising platform-based therapeutic candidates to minimize the effects of Ebola and Marburg virus infection.	<ul style="list-style-type: none"> <li>• FDA approval and initiation of First-Time-in-Humans Clinical Trials for Ebola and Marburg therapeutics using platform technology</li> <li>• First-time implementation of Earned Value Management for development of therapeutic MCM against BWA</li> </ul>
Funded IND filing for a <b><u>broad-spectrum therapeutic candidate targeting influenza viruses</u></b> (including H1N1 and seasonal flu strains)	FDA-approved IND filing
First U.S. government agency to undergo the FDA's new animal model qualification process for recently filed initial data report on <b><u>non-human primate model of Ebola virus infection</u></b>	Qualified Animal Model available for product development (pending)

# JPM-TMT Funding Profile FY12-16

(Based on FY12 President's Budget)



Adv Dev \$K	FY12	FY13	FY14	FY15	FY16	TOTAL
<b>BA4</b>	\$83,569	\$79,823	\$86,173	\$83,736	\$77,210	\$410,511
<b>BA5</b>	\$20,062	\$36,449	\$85,627	\$117,735	\$99,493	\$359,366
<b>TOTAL</b>	<b>\$103,631</b>	<b>\$116,272</b>	<b>\$171,800</b>	<b>\$201,471</b>	<b>\$176,703</b>	<b>\$769,877</b>

BA4: Pre-Milestone B (aka MS B, Product Development Decision)

BA5: Post-Milestone B

# JPM-TMT Upcoming Business Opportunities



Opportunity	Estimated Release Date
Request for Proposal (RFP) for development of broad-spectrum medical countermeasures effective against six primary bacterial pathogens (anthrax, plague, brucellosis, tularemia, glanders, and melioidosis), near neighbors and unknowns.	FY12
Market Survey for platform-based medical countermeasures against hemorrhagic fever viruses (HFV).	FY12
Broad Agency Announcement (BAA) for development and demonstration of predictive modeling technologies and fieldable biological detection devices to better anticipate and respond to naturally occurring disease outbreaks and biowarfare agents.	FY12
<b>JPM-TMT 2012 Partnership Symposium</b> to address program Grand Challenges	<b>May 22-24, 2012</b>

JPM-TMT solicits proposals primarily through the Federal Business Opportunities (FBO) website. For up-to-date business opportunities, visit [www.fbo.gov](http://www.fbo.gov) or [www.jpmtmt.mil](http://www.jpmtmt.mil).

# From Surveillance to Solution: *Providing Response to Biothreats and Emerging Infectious Diseases*



## JPM-TMT Grand Challenges

**Integrate complimentary technologies to develop systems that predict, detect, identify and respond to biothreats.**

**Deliver broad-spectrum solutions that are agnostic to the threat.**



# Save the Date!

Visit us online: <http://www.jpmtmt.mil>



## JPM-TMT 2012 Partnership Symposium

May 22 – 24, 2012

Manchester Grand Hyatt | San Diego, CA



*Photo Courtesy of [www.navy.mil](http://www.navy.mil)*

**JPM-TMT partners** with other government agencies and laboratories, industry, and academia to facilitate the **advanced development and acquisition of broad-spectrum medical products and systems** to enhance our nation's response capability to biothreats and emerging infectious diseases.