



Joint Project Manager Transformational Medical Technologies Advanced Planning Briefing for Industry

September 7, 2011

"Protecting the Warfighter and the Nation from Biothreats."



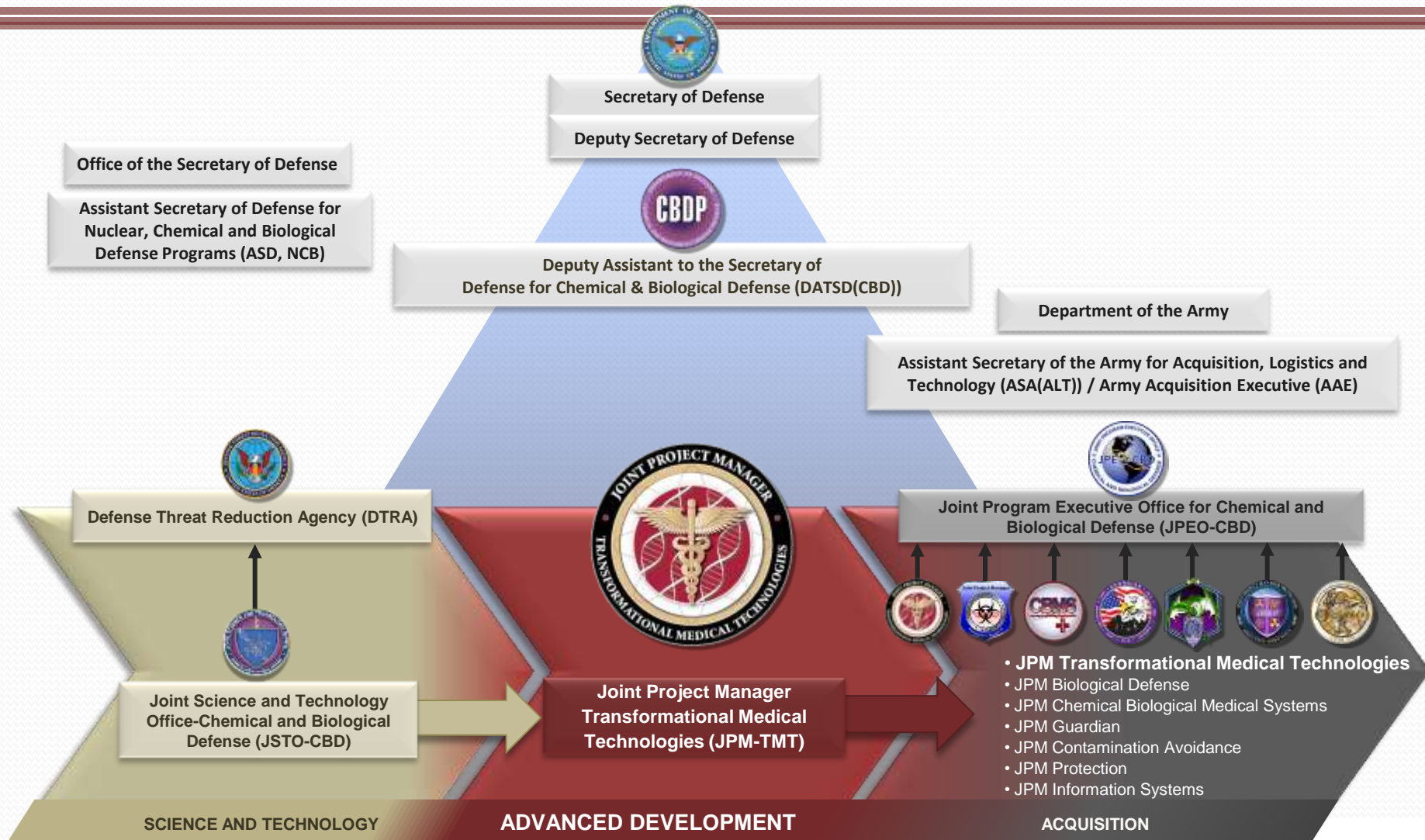
MR. DAVID E. HOUGH
Joint Project Manager, TMT



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:

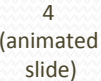
- Tularemia
- Botulism
- Junin
- Influenza

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:

FY09	FY10	FY11 – FY12	FY13	FY14	FY15	FY16	FY17 – FY18
IND	MS A	Phase I Clinical Trials	MS B	Pivotal Animal Efficacy	Phase II/III Expanded Human Safety Clinical Trials	NDA	FDA MS C Approval

Current Effort:

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

Follow-on Efforts:

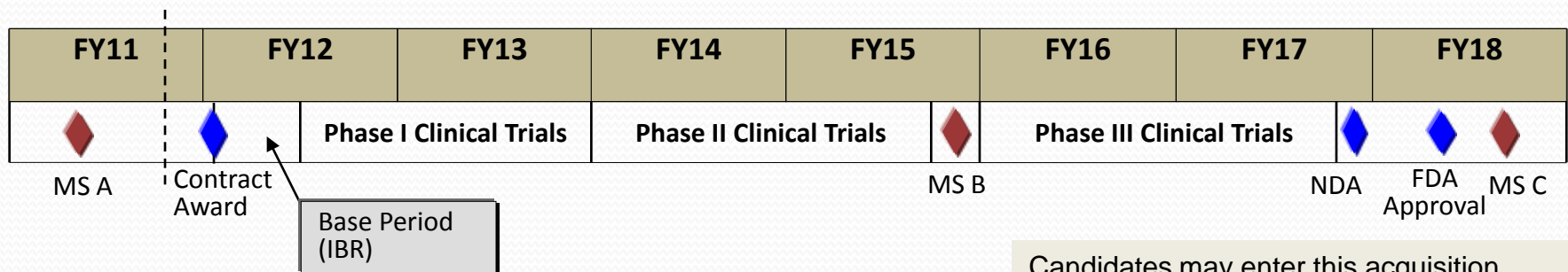
- Develop host immune enhancement viral countermeasure (FY 14 Initiation)
- Leverage platform technology against other Hemorrhagic Fever Viruses (HFV) in anticipation of HFV-like engineered biowarfare agents (BWA) (FY 17 Initiation)

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:



Current Effort:

- Source selection ongoing

Follow-on Efforts:

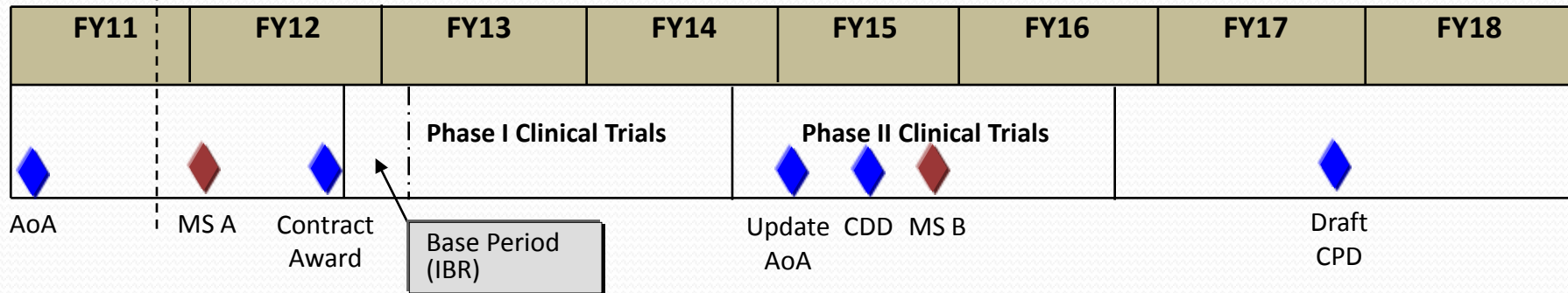
- Conduct an AoA at MS B to determine if new MCMs exist in the market place for potential inclusion in the EID program.
- Continue coordination with JSTO and industry for development of products for transition to advanced development for emerging infectious diseases.

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:



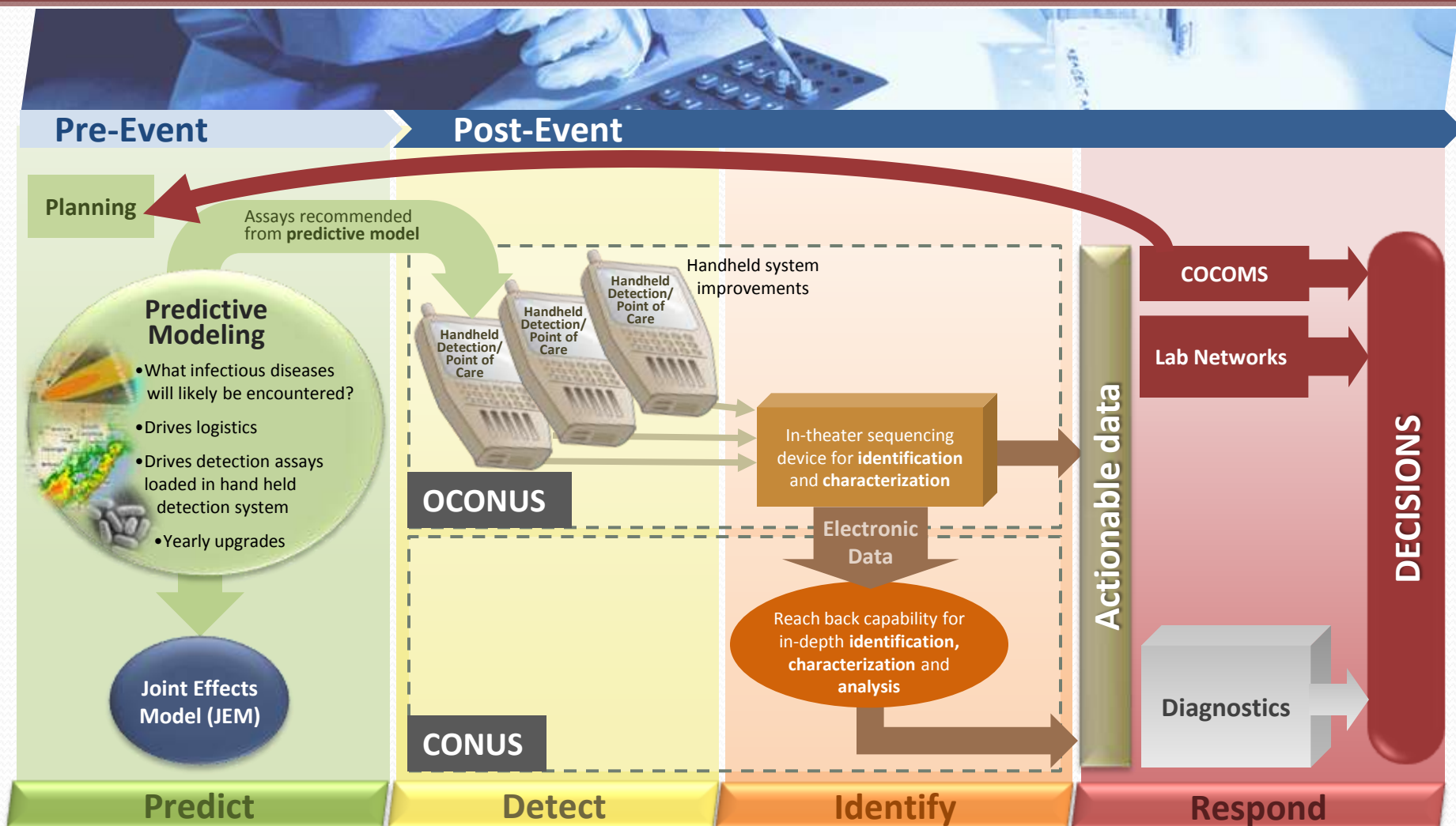
Current Effort:

- Preparing for MS A review 1Q FY12.

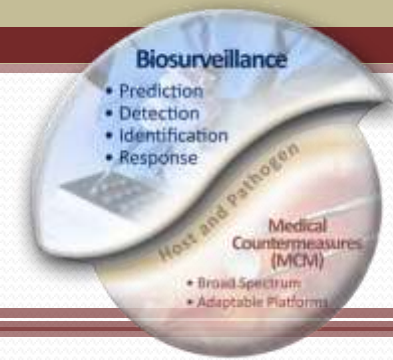
Follow-on Effort:

- 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...”

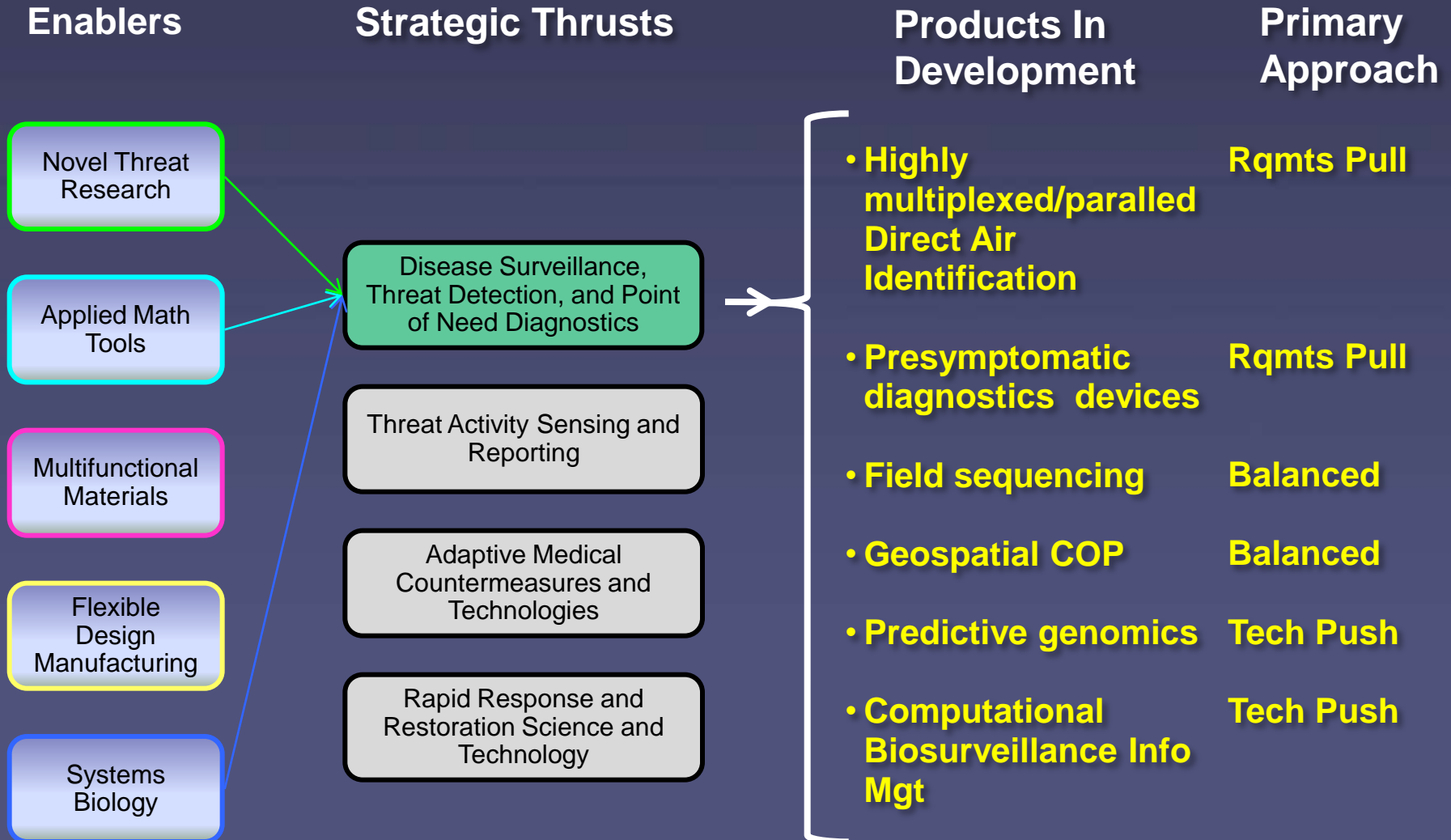
Mr. Andy Weber

CBDP FY 2012-2017 Program Strategy Guidance





A CLOSER LOOK: BIOSURVEILLANCE AND DIAGNOSTICS





Disease Surveillance and Future Diagnostics

CBRN

AGENT/HOST TARGET IDENTIFICATION

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

ENABLING CAPABILITIES

Sample
Prep &
Preserve

Platform
Technologies

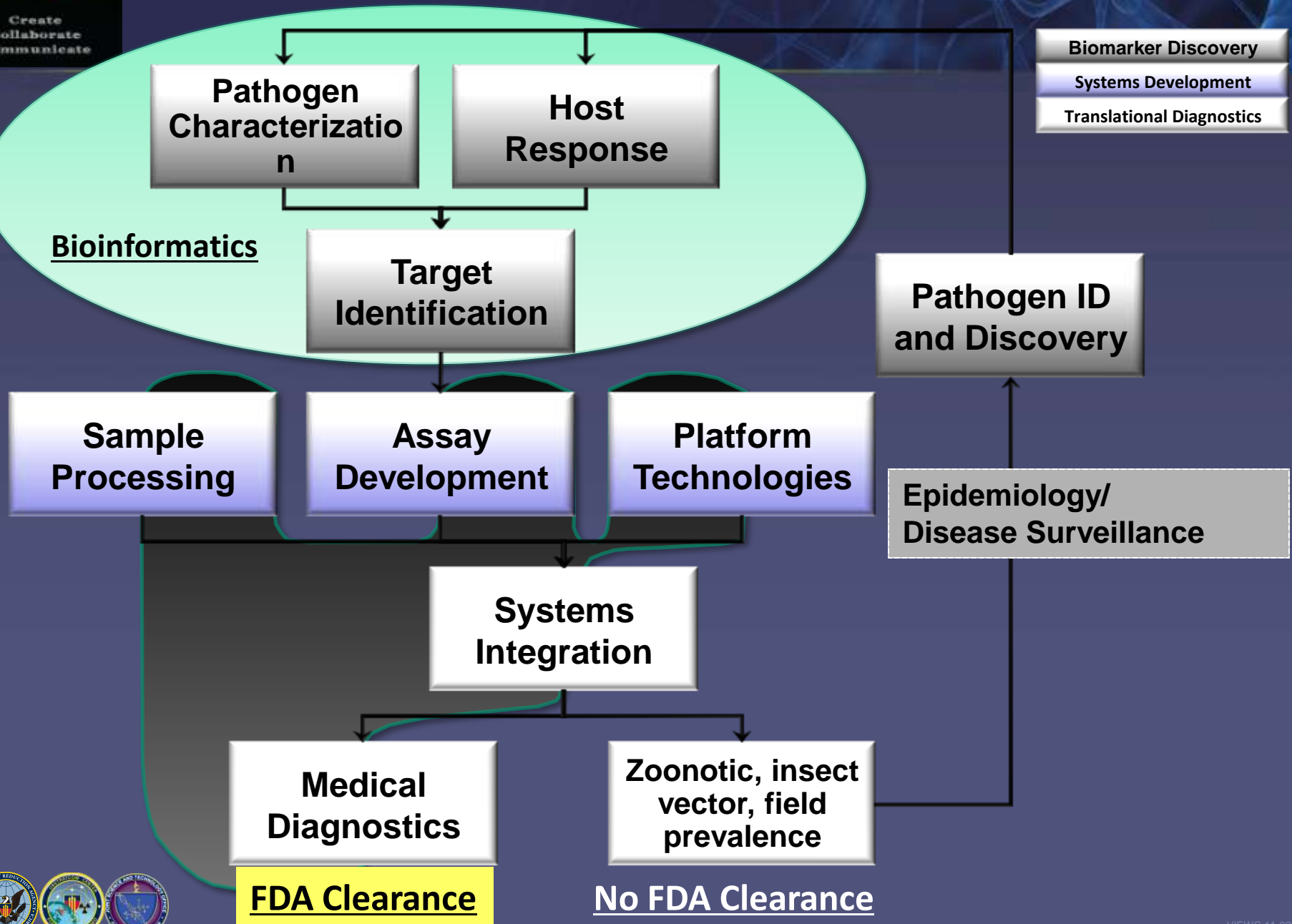
Engineering/Performance Drivers

**Future
Systems
Development**

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



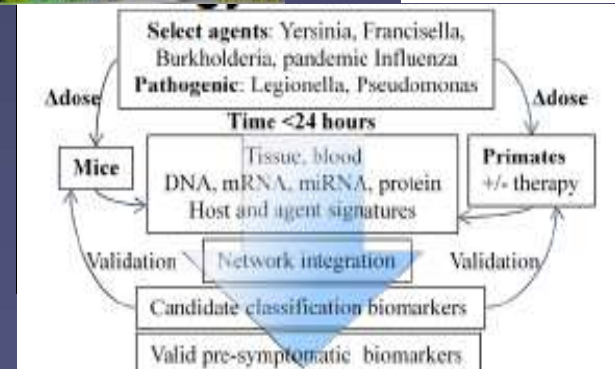
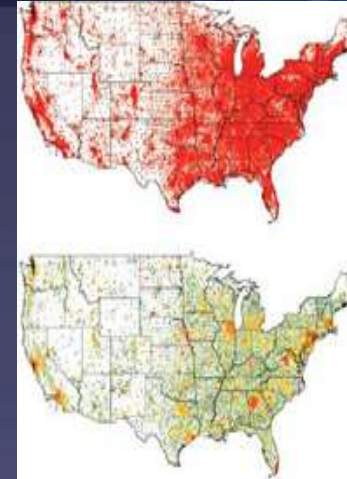
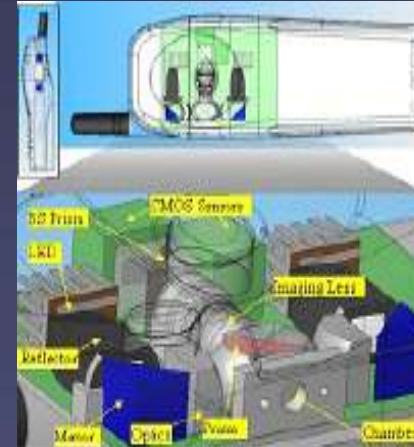
Diagnostics and Disease Surveillance Division





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

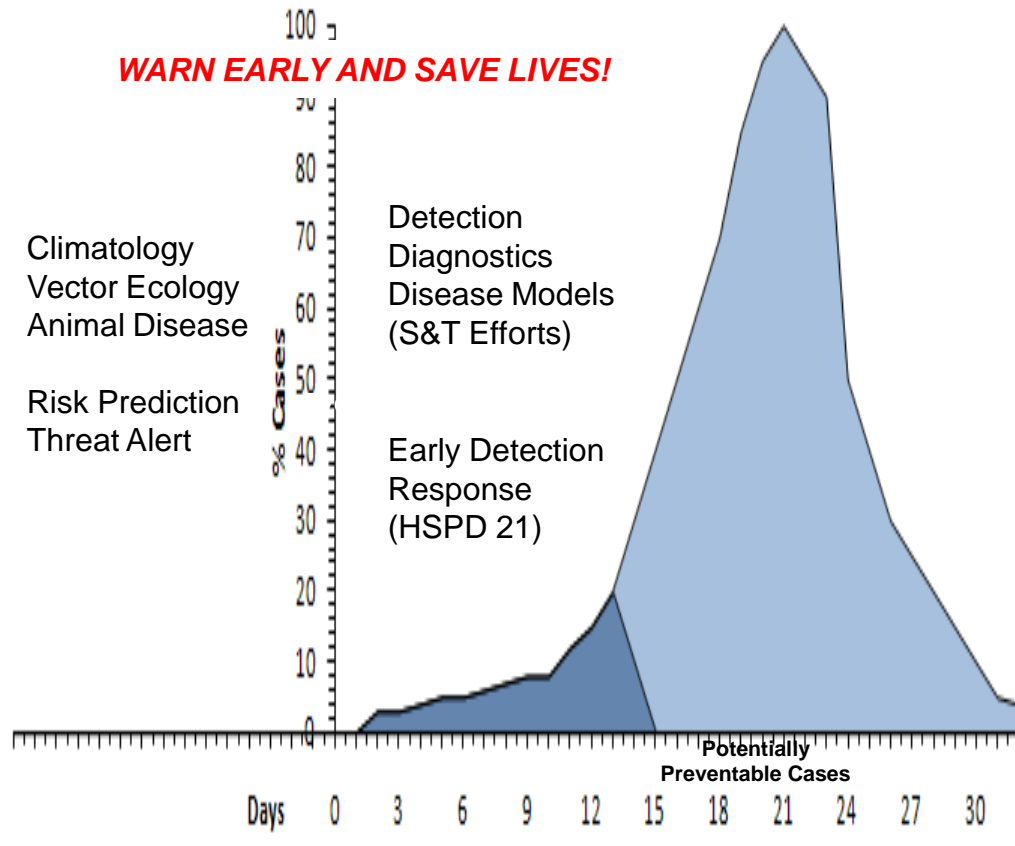




Biosurveillance: Focus and Top-Line Investment



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

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

Detection

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

'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

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

Characterize Agent

Phenotype, Genotype, Persistence

Future Diagnostic

Human Response Biomarkers
amenable to FDA

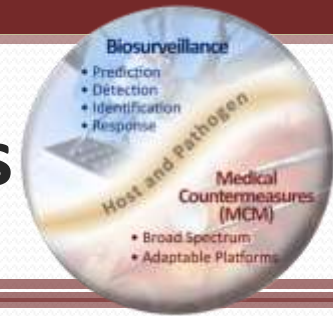
Geospatial COP

Convert boundaries and population
dynamics into disease recognition

Projects



JPM-TMT Innovations and Successes



Innovations	Successes
Successful completion of <u>rapid-response integration exercises</u>	<ul style="list-style-type: none"> • Bacterial and viral threats (18 days) • Dengue virus (11 days) • H1N1 pandemic (7 days)
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"> • FDA approval and initiation of First-Time-in-Humans Clinical Trials for Ebola and Marburg therapeutics using platform technology • First-time implementation of Earned Value Management for development of therapeutic MCM against BWA
Funded IND filing for a <u>broad-spectrum therapeutic candidate targeting influenza viruses</u> (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 <u>non-human primate model of Ebola virus infection</u>	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
BA4	\$83,569	\$79,823	\$86,173	\$83,736	\$77,210	\$410,511
BA5	\$20,062	\$36,449	\$85,627	\$117,735	\$99,493	\$359,366
TOTAL	\$103,631	\$116,272	\$171,800	\$201,471	\$176,703	\$769,877

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
JPM-TMT 2012 Partnership Symposium to address program Grand Challenges	May 22-24, 2012

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

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.