

create
collaborate
communicate



“Investing in
transformational ideas,
innovative people, and
actionable technology
development for Chemical
Biological Defense
solutions”

DEFENSE THREAT REDUCTION AGENCY

JOINT SCIENCE AND TECHNOLOGY OFFICE

CHEMICAL AND BIOLOGICAL DEFENSE

NCB Industry Group
April 19 2012



협조해 주셔서 감사합니다.

According to Article 21 of Aviation Safety/Security Act, carrying weapons (including biochemical weapons such as anthrax, smallpox germ), swords, toxic chemicals, explosives or flammable materials, etc. into the aircraft is prohibited.

All passengers must be screened at security checkpoint, otherwise boarding could be declined.

Thank you for your cooperation.

JSTO Strategic Plan

Outcomes

#1 Deliver S&T Products and Capabilities that outpace the threat

Deliver operationally relevant technology for the war fighter

Develop and sustain technical and scientific knowledge for the CB community

Thrust #1: Biosurveillance, Threat Detection, Point of Need Diagnostics
Thrust #2: Adaptive Medical Countermeasures and Technologies
Thrust #3: Threat Activity Sensing and Reporting
Thrust #4: Rapid Response and Restoration Science and Technology

Business Management Professionals

#2 Optimize Business Processes to Achieve Operational Excellence

Partner in translational teams

Leverage & cultivate partner capacity

Enhance integrated portfolio management

Integrated communications & enterprise reporting

Ensure fiscal integrity and agility

People

#3 Invest in our People

Develop world-class leaders and experts to deliver for our customers



Planned S&T investments are integrated across Divisions by Thrust Area or Enabling Sciences

Diagnostics and Disease Surveillance Division

Translational Medicine Division

Advanced and Emerging Threat Division

Physical Science and Technology Division

Thrust #1: Biosurveillance, Threat Detection, Point of Need Diagnostics

Thrust #2: Adaptive Medical Countermeasures and Technologies

Thrust #3: Threat Activity Sensing and Reporting

Thrust #4: Rapid Response and Restoration Science and Technology

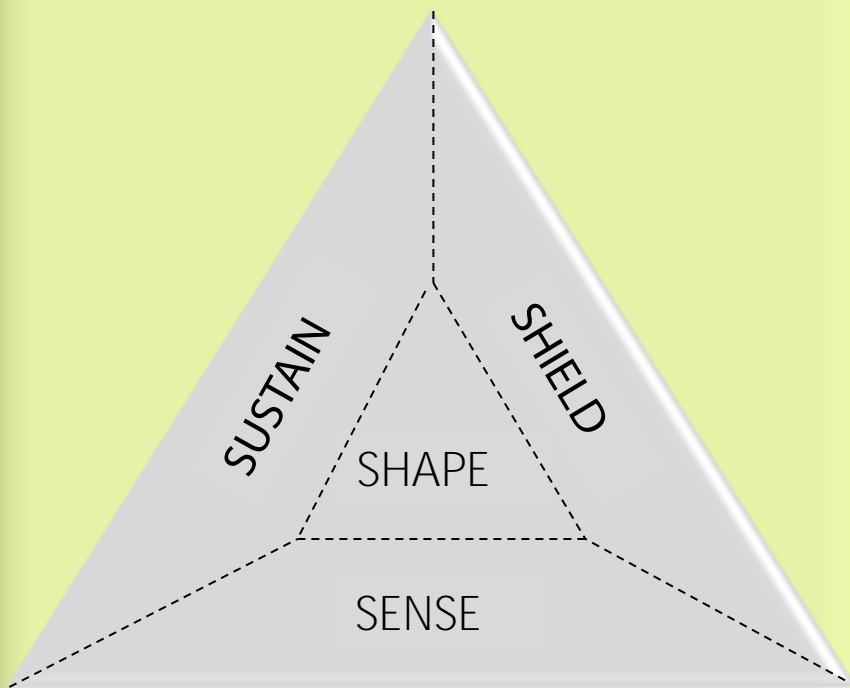
Enabling Sciences



S&T Plan: One Outcome through Five Objectives

Outcome

Deliver S&T products and capabilities that outpace the threat



Thrust 1 Objective: Protect mission capability and the Nation and save lives by providing essential information for better decision making at all levels

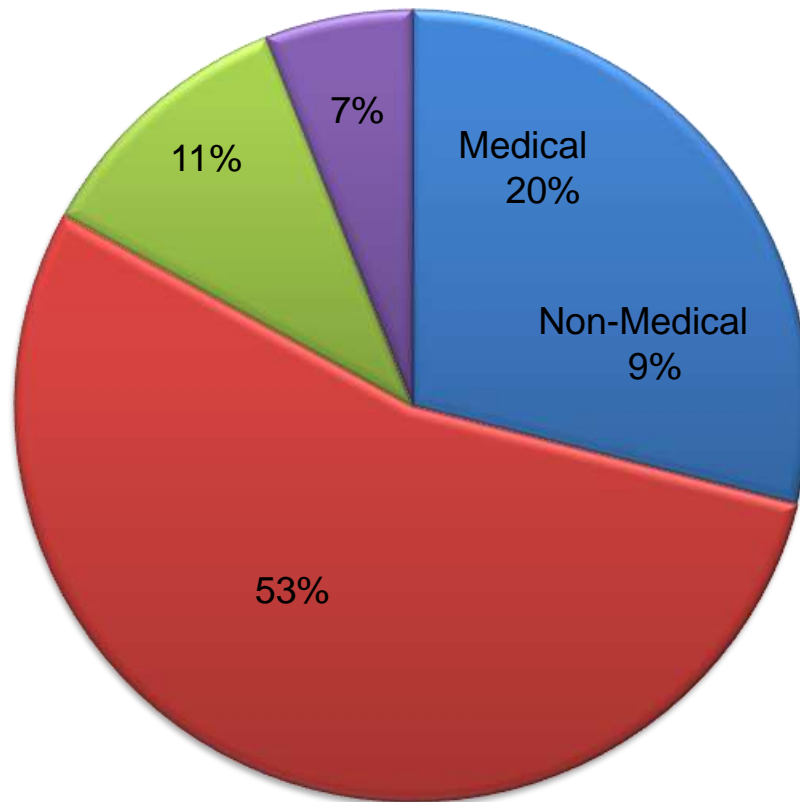
Thrust 2 Objective: Defeat chemical and biological threats to the warfighter and nation through translational medicine

Thrust 3 Objective: Characterize and monitor threat activity across the area of responsibility

Thrust 4 Objective: Rapidly recover personnel and equipment to operational status

Enabling Sciences Objective: Prevent technological surprise

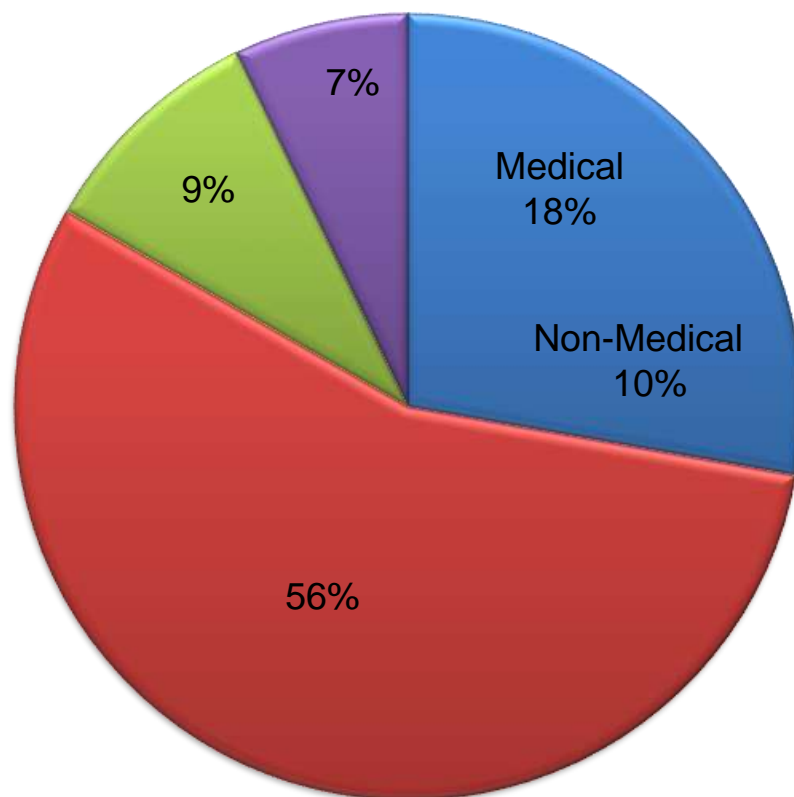
FY12 Funding Share



- Industry
- DoD
- OGA
- FIT



FY13 Funding Share



- Industry
- DoD
- OGA
- FIT

Our S&T focus

- Point of Need Diagnostics and the Convergence of Multiplexed Technologies to Generate High Information Content on Affordable Devices and Cellphones (Tier 0/1 devices)

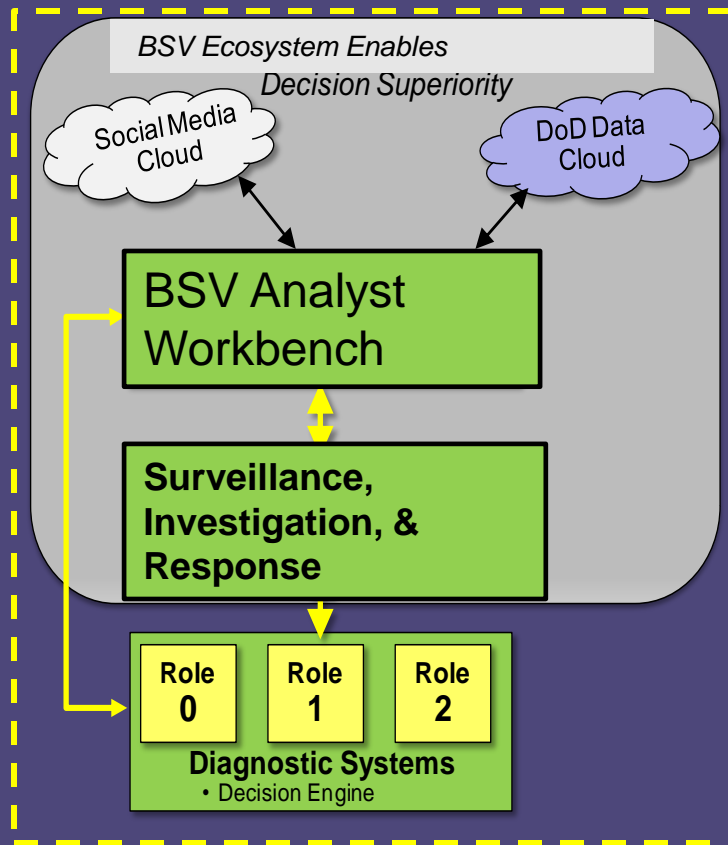
“push out the clinical lab into the field”

LINKED TO

- Novel Reporting Schemes that Integrate Open Source Information and Public Health/Private Sector Clouds

“exploit more rapid information flows”

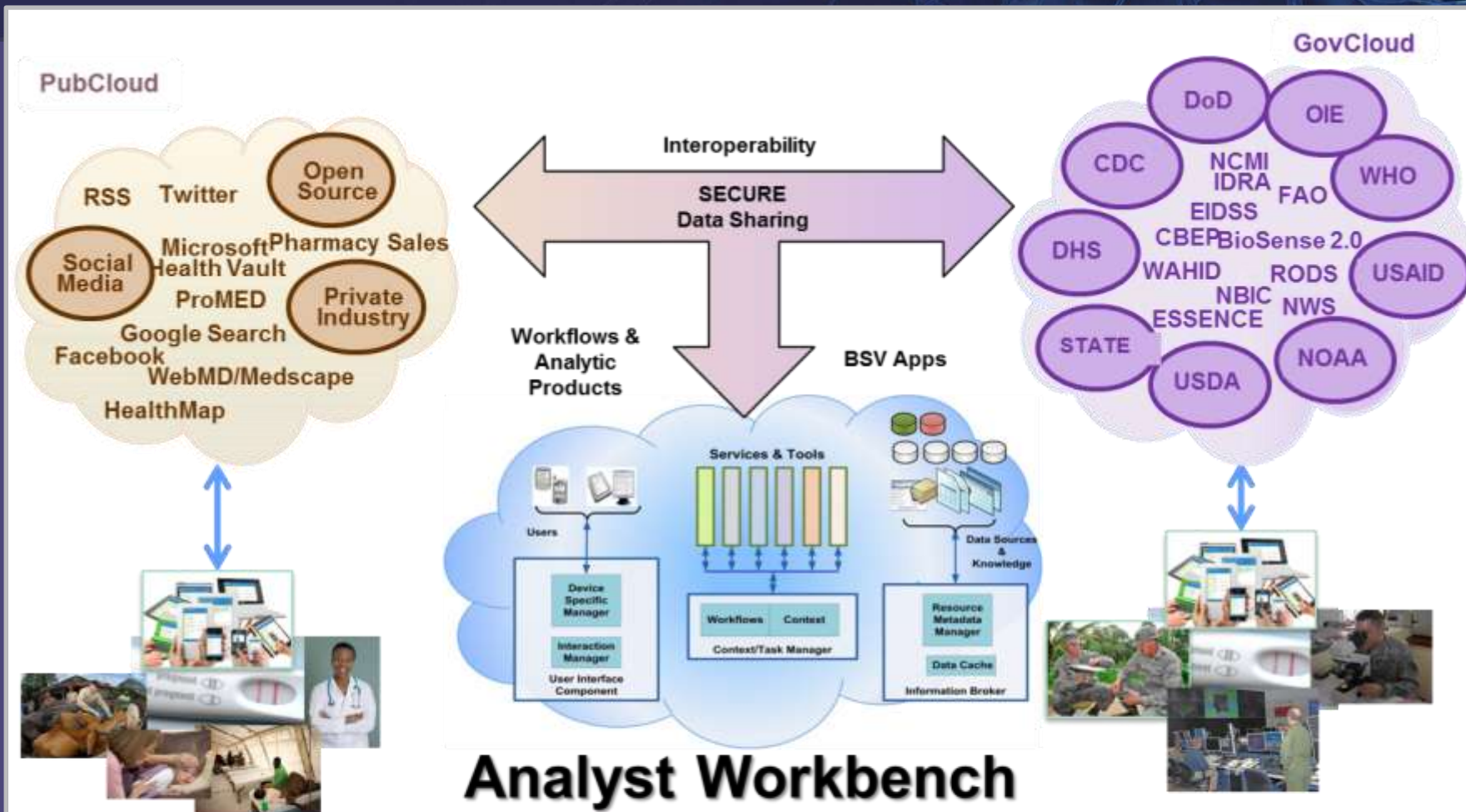
24-Month Challenge Objective



Scope of 24-Month Challenge encompasses a preliminary version of the BSV ecosystem and prototype Role 0/1 diagnostic systems

- **Speed**
 - Automated-but-verified open-source data discovery reduces notification time from weeks to days/hours
- **Accuracy**
 - Biosurveillance system verifies open-source reports with actual home/clinical-use device data
- **Cost**
 - Low cost of devices leads to ubiquitous distribution enabling earlier response and recovery activities

Biosurveillance Ecosystem



Ubiquitous Diagnostic Systems

Citizens (Role 0)	Med Staff (Role 1)	Soldiers (Role 0)	Med Staff (Role 1)
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Two Classes of Point of Need (PON) Diagnostic Systems Will Be Developed and Tested

- **Role 0:** very simple and rugged devices suitable for home / self-use by non-medically trained service members
- **Role 1:** handheld electronic systems for use in forward (medical level 1 care) environments

Role 0



HOME /SELF USE ¹

- Akin to paper-based platforms
- Capable of 3-5 tests on one sample

Role 1



MEDICAL PROVIDER

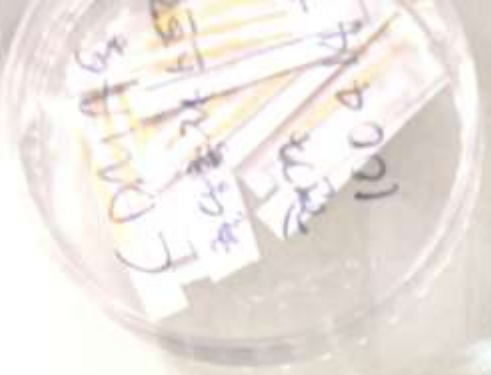
- Increased functionality
- Higher plexity (10-100 simultaneous tests)

Both classes are:

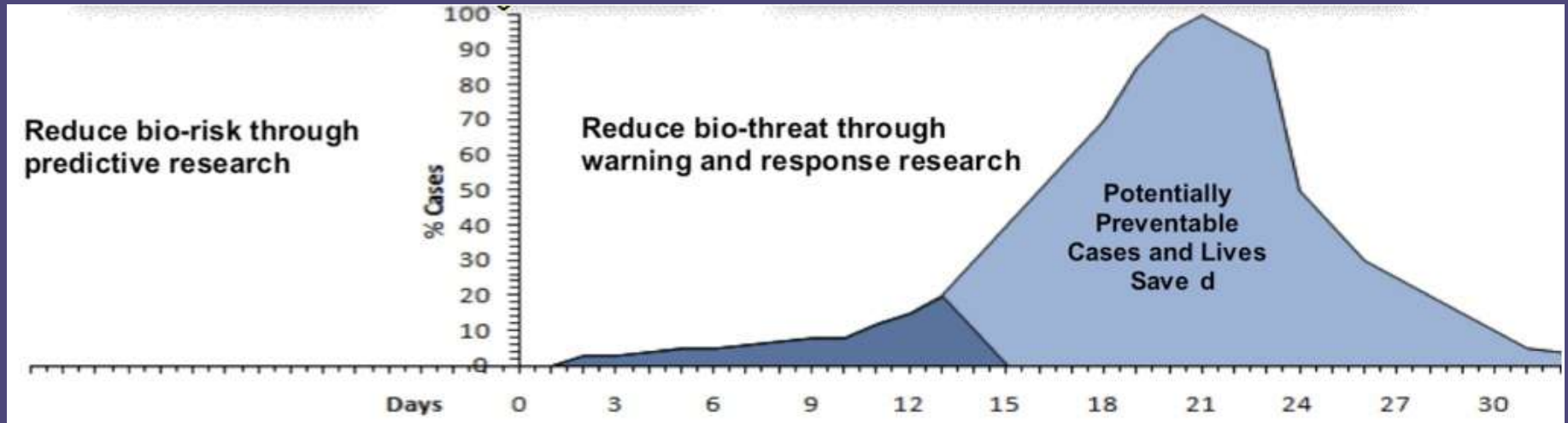
- Fast, easy to use, sample-to-answer systems
- Compatible with existing communications infrastructure²
- At clinical research stage in 24 months
- Suitable for eventual FDA clearance and CLIA waiver

1. Also includes uses with non-human samples (e.g. insect vectors, livestock, food, environment), which would be performed by technical operators

2. With use of external reader for Role 0 systems



A Typical Timeline of Response Today



Day 1 - 0 hr Release on subway
 + 4hr JPS and BIDS alarms indicate tularensis
 + 7hr PCR detection of tularensis

Day 2 – Samples sent to USAMRIID
 Swabs in 2 stations indicate tularensis
 Prophylaxis of presumptively exposed persons begins

Day 3 – soldiers diagnosed with flu or non-specific respiratory infections
 Swabs from several stations and ventilation ducts +ve for tularensis
 Subway system closed
 ROK President makes public announcement

Day 4 – Definitive tularensis identification by USAMRIID/CDC
 Clinical and environmental samples overwhelm analytical capacity

Day 5 – 10,000 patients presented
 Day 6 – Swabs +ve for tularensis in buildings near 2 subway stations
 Cultures from day 1 found doxycycline resistant
 21,000 patients



What Do We Want to Know on Day 1?

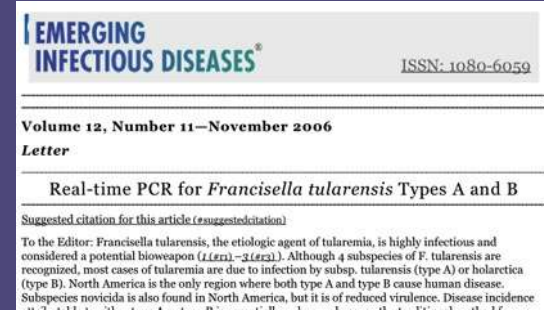
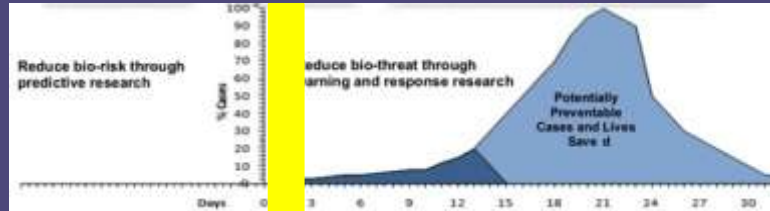
- What biological pathogens were released?
 - Single or mixture
 - Strain (type A tularemia 100x more virulent than type B)
 - Viability after aerosolization?
- Are these pathogens antibiotic resistant or engineered?
- Can I predict areas contaminated by known release?
- Does actual contamination pattern indicate >1 release?
- Can I start data-driven decontamination / response?
 - What sections of subway system affected (not whole system)?
 - What part of Seoul population exposed (not whole population)?
 - What areas affected, what are their demographics (high risk groups like schools)
 - What factual data inform response (data enriched day by day)?



Scenario-driven Response



Day 1
0 hr Release on subway
+ 4hr JPS and BIDS alarms indicate tularensis



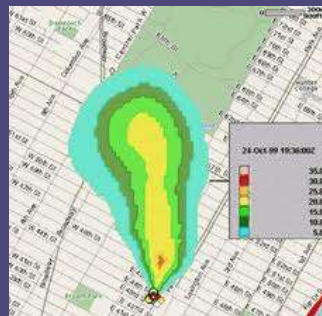
+ 7hr PlexID – +ve tularensis type A, doxycycline resistant, not a threat agent mixture (also determines infectious etiologies of non-specific respiratory infections)

Suitcase contents analyzed by PlexID, also for bacterial viability after aerosolization and potential amount released



Text in yellow identifies new BSV data from S&T

Modeling of potential spread in subway and around exhaust vents and entrances - models informed by real time sampling data



Real time GPS mapping of subway and air system contamination and systematic local air sampling (portable samplers GIS-located) around exhaust vents using tier 0 tests and electronic reporting into Command and Control Center

7 hr PCR +ve tularensis type A

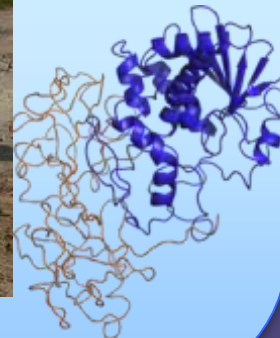
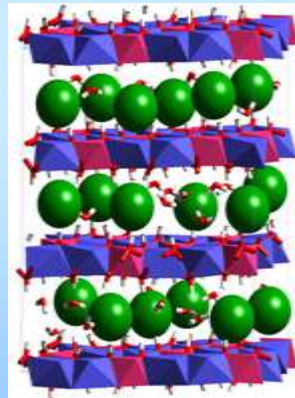
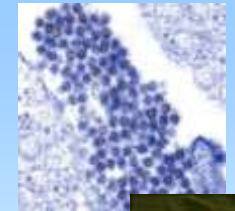


Environmental Response

Characterize mechanisms and predict the behavior of threat agents in the environment

Objectives

- Characterize CB threat agents and classify based on properties
- Quantify persistence and reactivity for threat agents in operationally relevant environments
- Understand environmental effects on threat agent transport and permeation
- Assess impact of threat agents on material
- Identify conserved traits of organisms propagated under artificial conditions to distinguish between natural and anthropogenic history
- Elucidate impact of environmental, vector and reservoir stressors on genotypic and phenotypic evolution, survival, and dispersal



Impact: Enhanced operational assessments of agent behavior, detection, decontamination and hazard quantification.

IDEAS FROM NOVEL SOURCES



Citizen Science Program

- Access to technology and information has created a Citizen Science community. DIY Bio is one exemplar.
- Involvement increases JSTO's opportunity to source innovative approaches and people
- Citizen science has potential to empower and inform public to respond.

Program	Description	Target Audience	JSTO Technical Area
BioHacker Challenge Days	Issue bioinformatics big data challenges in a one day event for teaming, coding and algorithm development	Computer science, Math Students and Professionals	Diagnostics, Detection
Assay Depot Challenge	Stimulate entrepreneurs in synthetic biology to address JSTO challenges with little capital	Entrepreneurs in community biological laboratories	Detection, Diagnostics, Decontamination
iGEM Engagement	Stimulate students in synthetic biology to address JSTO challenges	Undergraduate students	Detection, Diagnostics, Decontamination
Citizen Science	Leverage community efforts in air quality monitoring to create a network of low-cost sensors for the DoD	Community Groups, Technology hobbyists, students	Detection



Biohacker Challenge Days: Issue Bioinformatics Big Data Challenges To Math And Computer Science Professionals

Opportunity:

Engage in 'Hackathons' to solve Bioinformatic Chem-Bio Problems

Ex: Algorithm challenge in signal/noise biomarker data



Potential Benefits:

- Introduce technically saavy people outside of biology to work on biological issues.
- Seed ideas for novel bioinformatic tools and algorithms of value to the DoD.

Community Biology Labs

Program:

- Support open call for proposals at community laboratories in synthetic biology
- JSTO will select a proposal in one of the following areas:
 - Detection (E.g. Water Canary – A water quality sensor that can be built at home for <\$200; currently in use in developing nations)
 - Identification
 - Remediation

Benefits:

- Engage new performers that bring orthogonal and novel thinking to DoD challenges
- Find affordable solutions to DoD challenges



Community Garden



Community Biology Laboratory (GenSpace, NYC)

Harvesting next generation biotechnologists

Background:

- iGEM (international genetically engineered machine) is the premiere undergraduate synthetic biology competition
- Began in 2003 with ~30 participants as an intersession class at MIT.
- In 2011, 160 teams from 30 countries
 - Winners: Slovenia (2006, 2008, 2010), China (2007), UK (2009), USA (2011).
 - iGEM teams have created over 2000 genetic 'parts' that reside in a registry
- iGEM participants now shape the synthetic biology industry. They have founded or work at:
 - Gingko Bioworks, CoFactor Bio, BIOFAB, etc.
- iGEM produces more new practitioners in synthetic biology than any other venue.

JSTO has supported iGEM and are sponsoring a program to curate the registry of parts

Benefits:

- Create solutions for JSTO technical challenges
 - Recently JSTO endorsed the continued development of an iGEM project which genetically engineered nematodes to digest anthrax spores in long term wide area decontamination of soil



Strategic Thrust: Adaptive Medical Countermeasures

Pre-Event

EVENT

Post-Event

Post-Exposure,
Pre-Symptomatic

Symptomatic

Wide Spectrum Rx Threat and Host Strategies:

Anti-virals, Anti-bacterials, Host Immunomodulators, Chem/Rad Therapeutics

Pretreatments

Dx-Directed Treatments
& Countermeasures

Therapeutics

Antibiotic
Resistance
Markers

Pre-symptomatic
Biomarkers

Host
Biomarkers

Pathogen ID

High Content Data Backbone

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

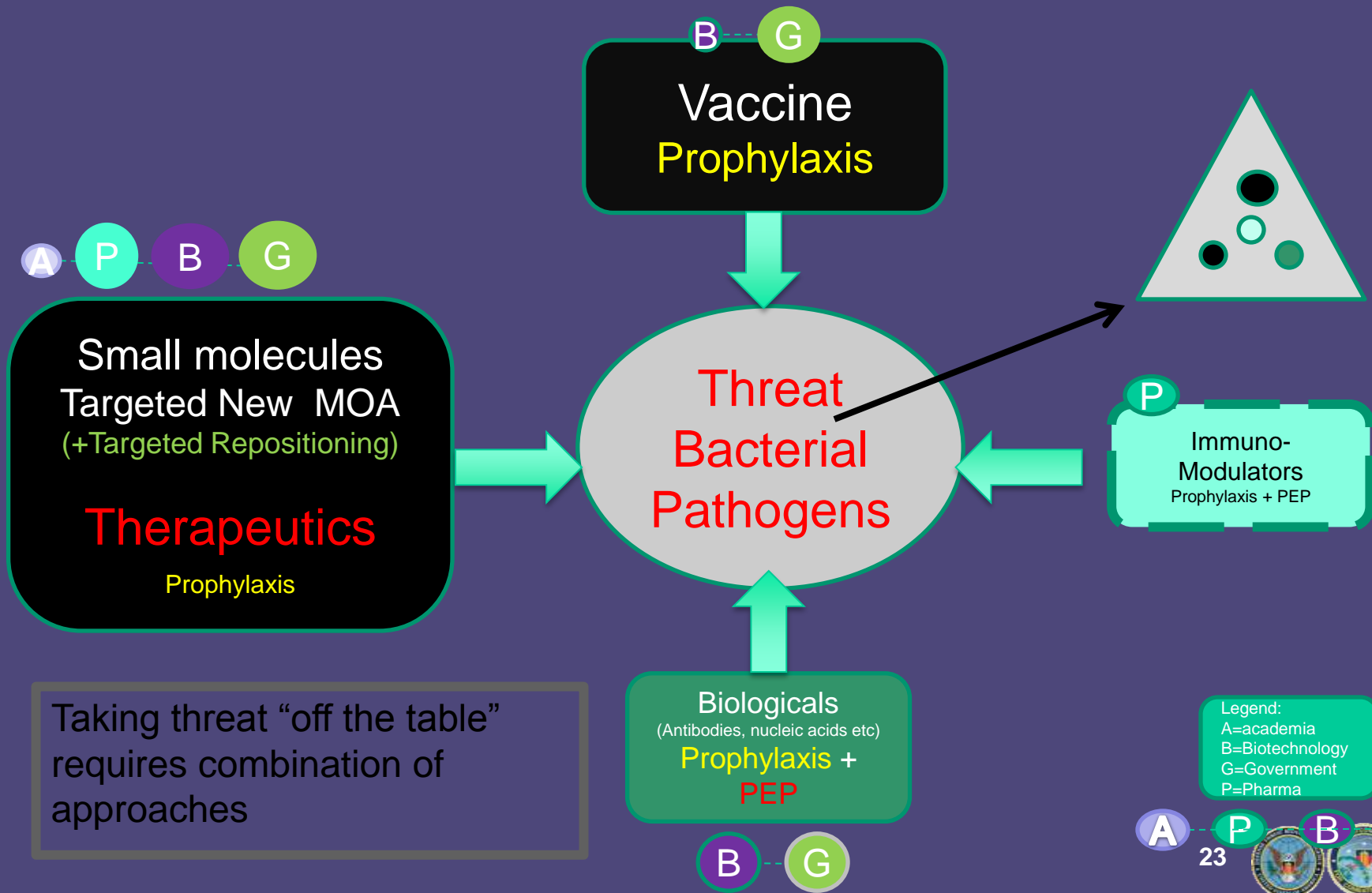
Flexible
Adaptive
Manufacturing

Regulatory
Sciences

Disease
Targets



Tactics & Key Performer Contributions for Preparedness Against MDR Weaponized Viral Threats



Translational Medicine S&T Responsibility and Risk Reduction

Establish early criteria and translational teams for robust transition

Team 1: S+T ad Team 2: S+T AD

Team 3: AD + s+t

Minimum Criteria

PK/PD in relevant animal models

Pre-clinical Safety & Efficacy (NHP)

Therapeutic Index for Military Utility

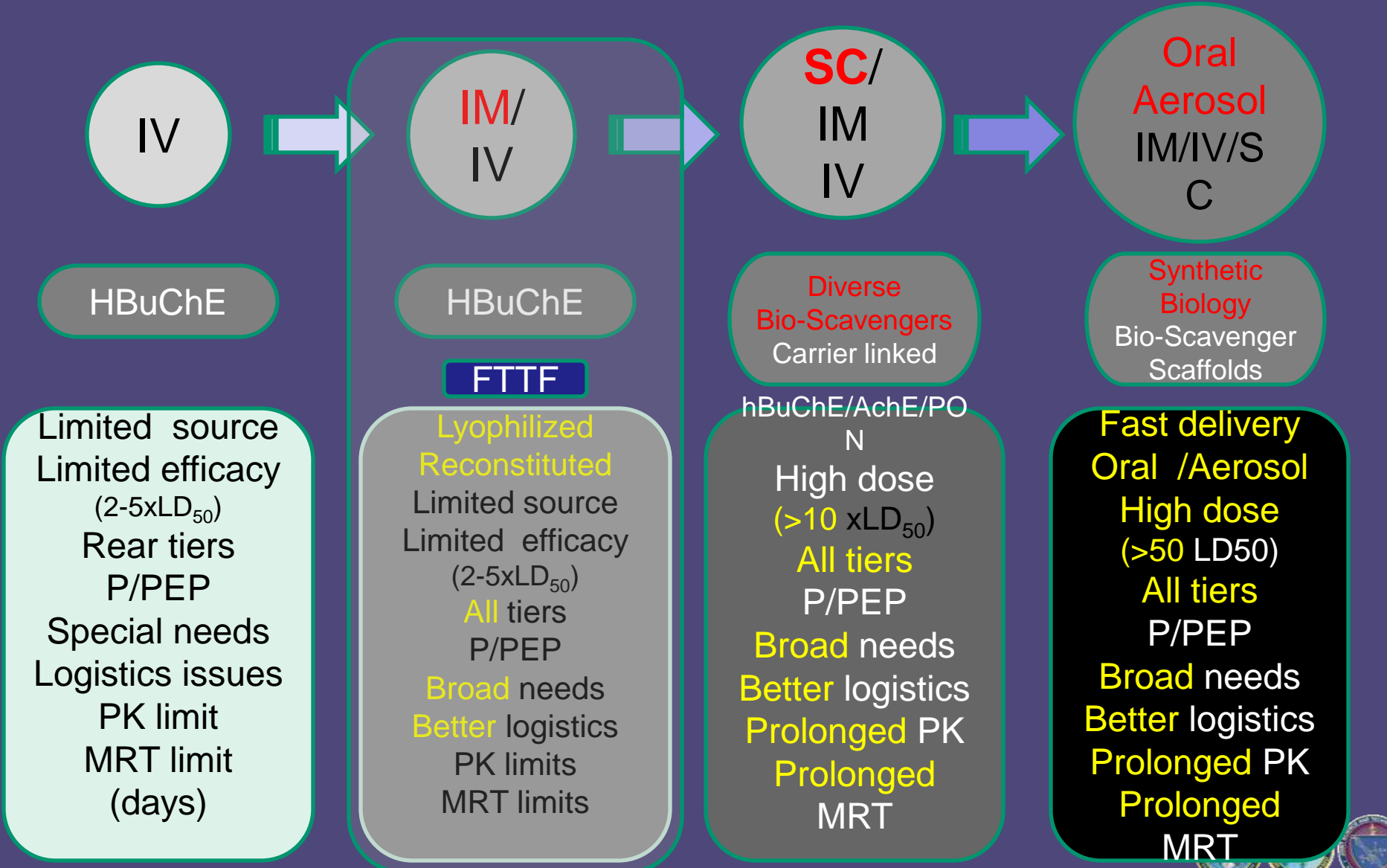
Route of Administration

Standard of Care comparisons

Biomarker utility

Robust
Decision to
Human Phase
I studies

Life Cycle Development of Protein Derived, Bio-Scavenger Based, Anti-NAs Prophylaxis/PEP



Summary

- DoD S&T requires innovation from a variety of sources
- Biological and chemical threats create opportunities and challenges for the DoD performer base
- Fundamental research investments feed important applications in chemical and biological defense
- Industrial partnerships are a key to our success

