

create  
collaborate  
communicate



**WHAT WILL BE  
DIFFERENT NEXT TIME?**

**PREPARING FOR  
BIOLOGICAL AND  
CHEMICAL THREATS**

DEFENSE THREAT REDUCTION AGENCY

JOINT SCIENCE AND TECHNOLOGY OFFICE

CHEMICAL AND BIOLOGICAL DEFENSE

International Conference on Health and Security  
Dr. Alan Rudolph  
September 5, 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.





# Community Biology Labs

## Program:

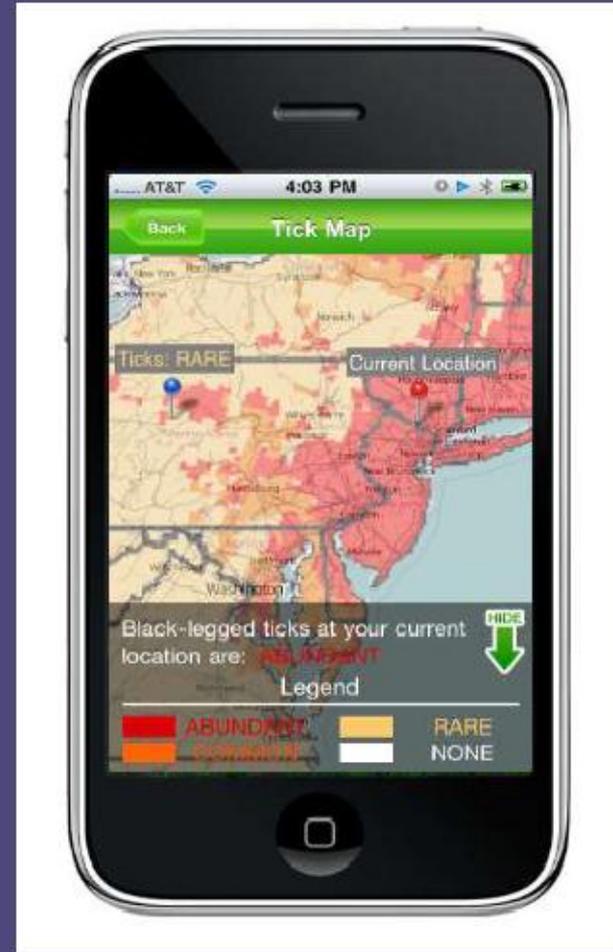
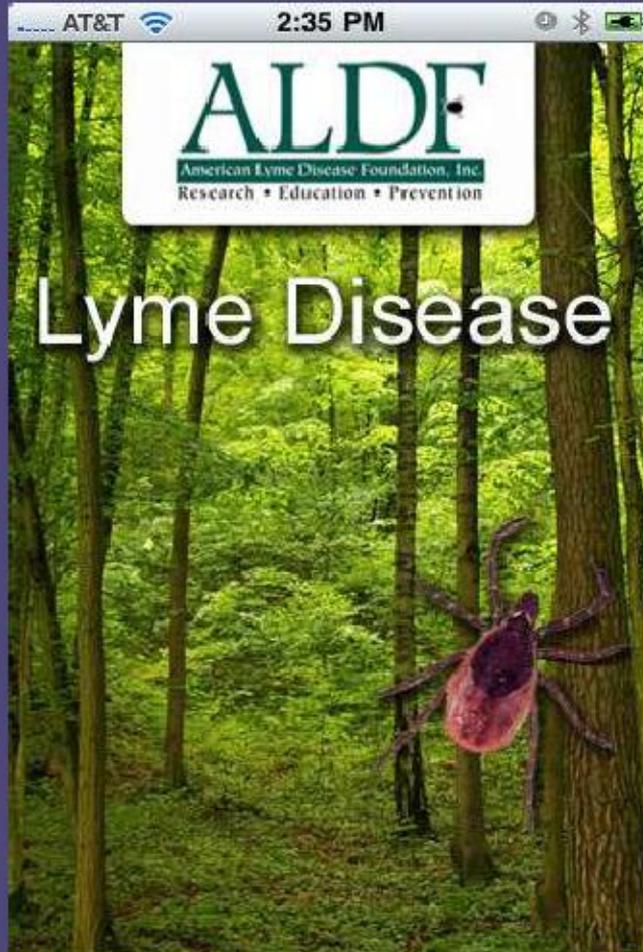
- Support open call for proposals at community laboratories in synthetic biology
- JSTO will select a proposal in one of the following areas:
  - Detection (E.g. Water Canary – A water quality sensor that can be built at home for <\$200; currently in use in developing nations)
  - Identification
  -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

## Benefits:

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







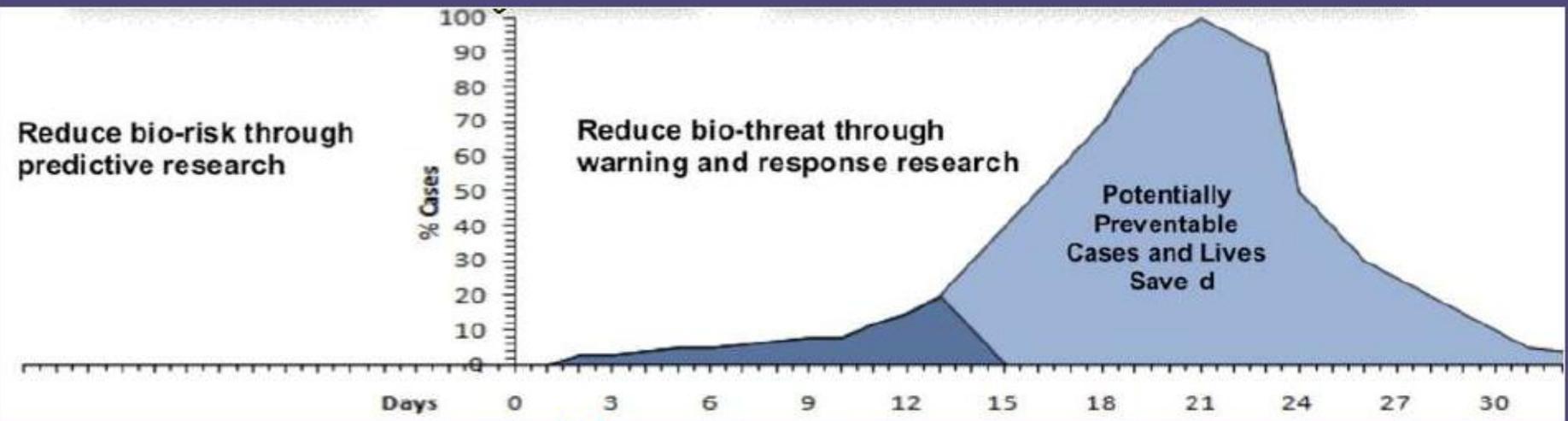
## CHALLENGE

Our current biosurveillance systems do not provide us with early warning....

we only learn about what happened  
**after it is too late.**



# A Current Scenario of Response



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

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

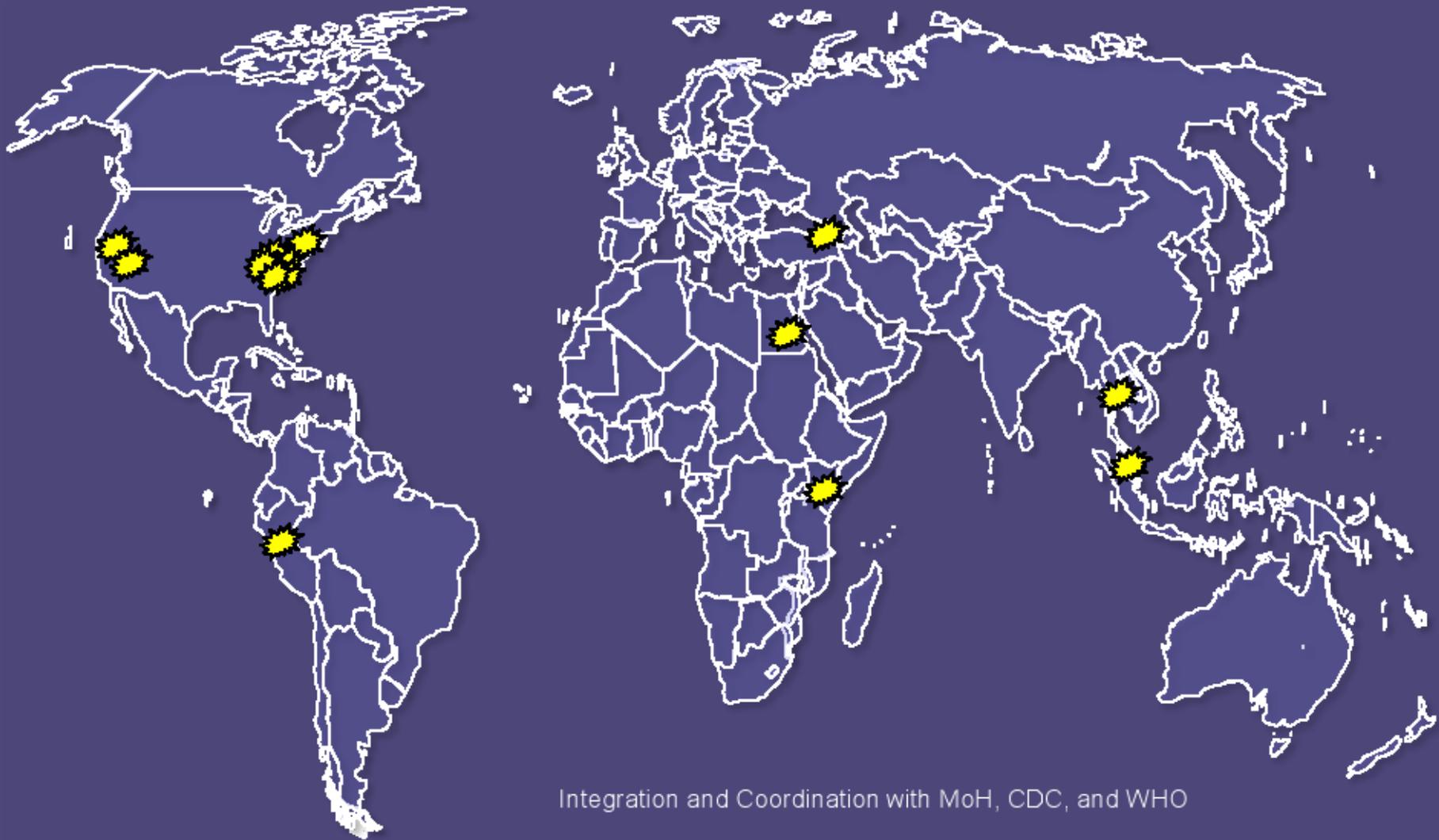
Day 3 – soldiers diagnosed with flu or non-specific respiratory infections  
 Swabs from several stations and ventilation ducts +ve for tularensis  
 Subway system closed  
 ROK President makes public announcement

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



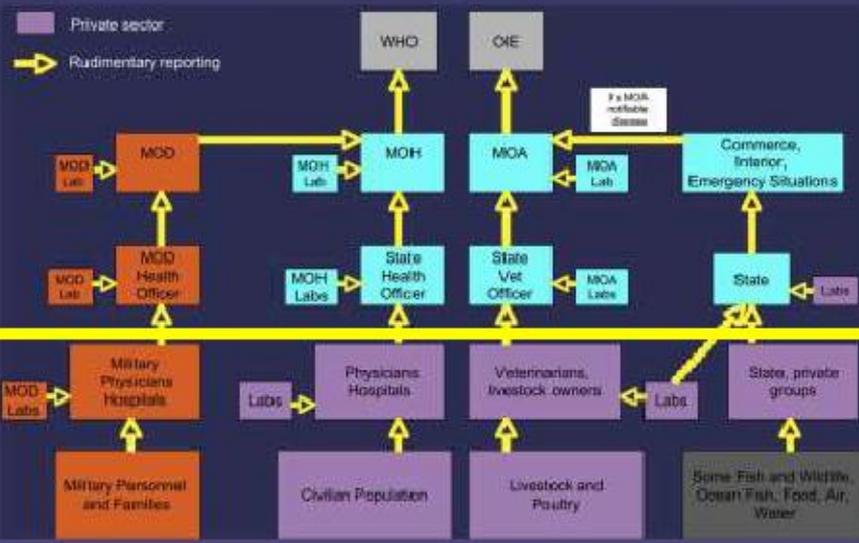
# BSV Test Bed Network Based on Engagement in CONUS and OCONUS Labs and Clinics



Integration and Coordination with MoH, CDC, and WHO

# Many New Opportunities for Real Time BSV Data Collection, Reporting, and Integration

## Official Surveillance and Reporting Channels



## Informal Surveillance and Reporting Channels

- Press, TV, radio, other
- Scientific literature, reports, books
- ProMed mail and similar
- HealthMap and similar
- Aggregation sites (GPHIN)
- Blogs, websites
- Expert Forums - Malaria World
- Google, Twitter
- Facebook, etc

- Individuals
- Self-assembled interest groups
- Academic, government and private sector entities (UNHCR, UNICEF, MSF, VSF etc)

Technology has removed the gatekeepers to information from the lowest levels – DoD is not generating the data

|                 |          |                                      |                           |                           |                              |                                |                                |
|-----------------|----------|--------------------------------------|---------------------------|---------------------------|------------------------------|--------------------------------|--------------------------------|
| Deployed Forces | War Zone | Known and Unknown Pathogens & Toxins | Known and Unknown Targets | Known and Unknown Vectors | Known and Unknown Reservoirs | Known and Unknown Risk Factors | Known and Unknown Host Factors |
|-----------------|----------|--------------------------------------|---------------------------|---------------------------|------------------------------|--------------------------------|--------------------------------|

### THE GLOBAL ENVIRONMENT - BOTH LAND AND SEA



Weather      Land use      Human census data      Temperature      Vegetation



# 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 <sup>1</sup>**

- 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)

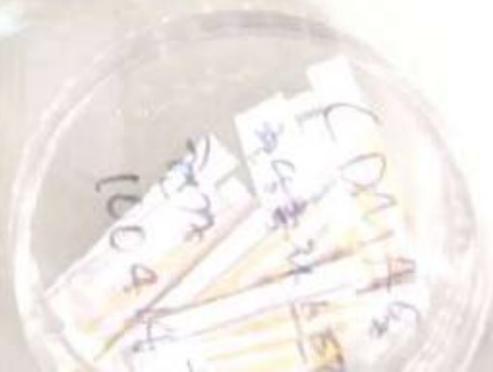
Both classes are:

- Fast, easy to use, sample-to-answer systems
- Compatible with existing communications infrastructure<sup>2</sup>
- At clinical research stage in 24 months
- Suitable for eventual FDA clearance and CLIA waiver

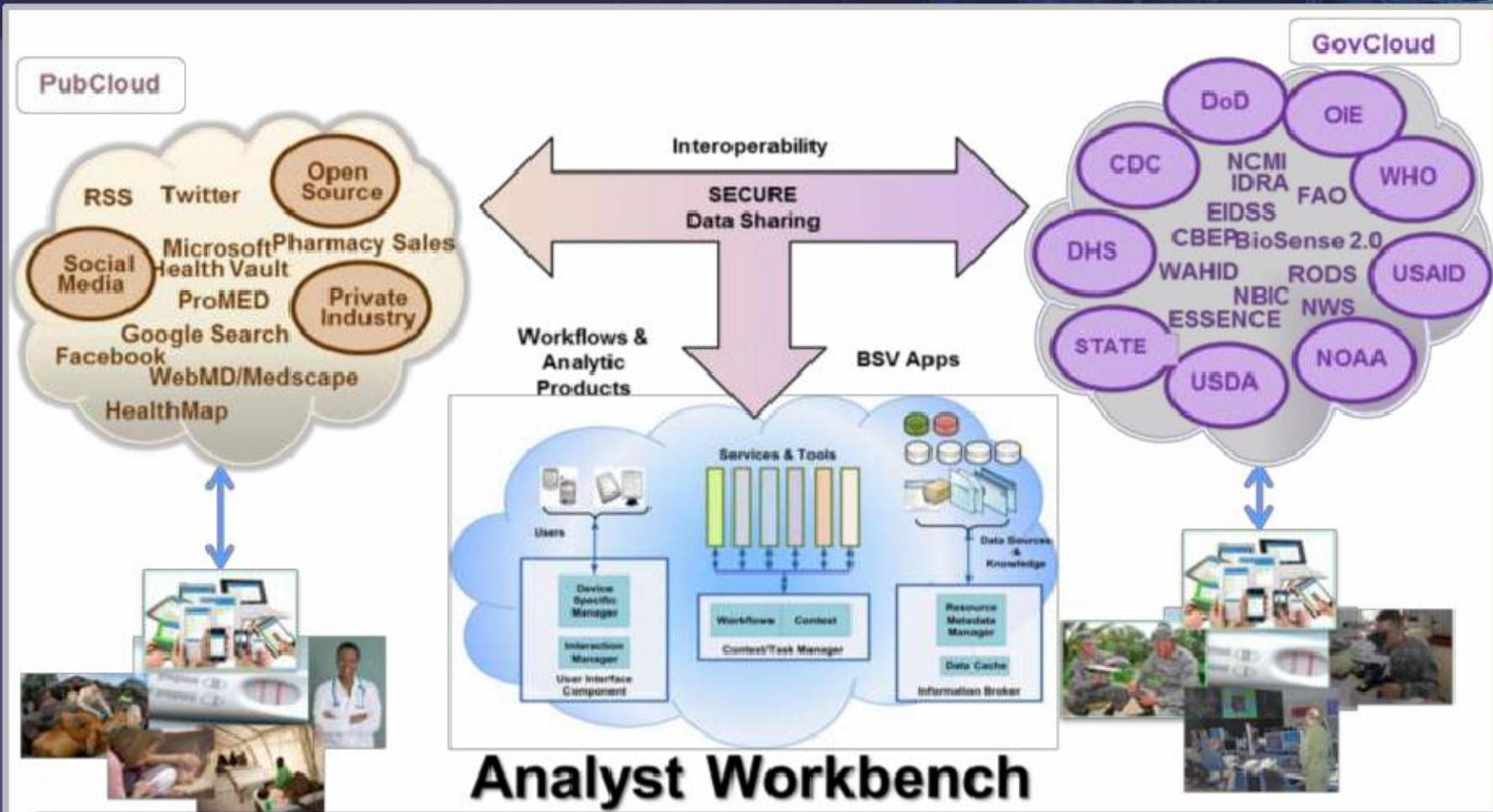
1. Also includes uses with non-human samples (e.g. insect vectors, livestock, food, environment), which would be performed by technical operators

2. With use of external reader for Role 0 systems

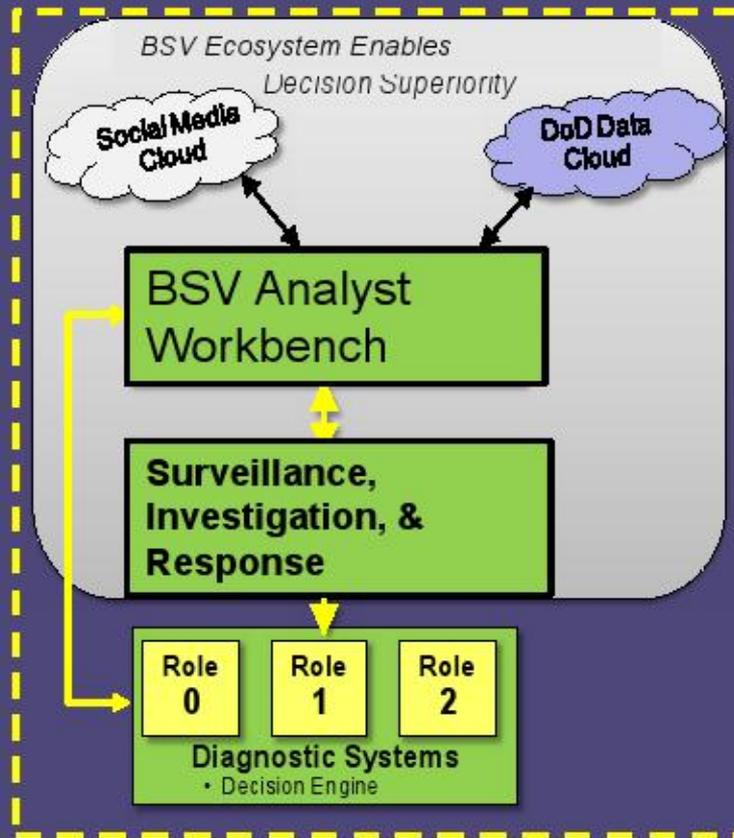




# BIOSURVEILLANCE ECOSYSTEM



# 24-MONTH CHALLENGE OBJECTIVE



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

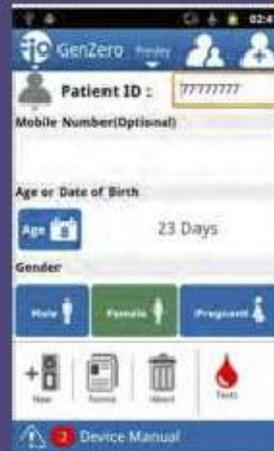
- **Speed**
  - Automated-but-verified open-source data discovery reduces notification time from weeks to days/hours
- **Accuracy**
  - Biosurveillance system verifies open-source reports with actual home/clinical-use device data
- **Cost**
  - Low cost of devices leads to ubiquitous distribution enabling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



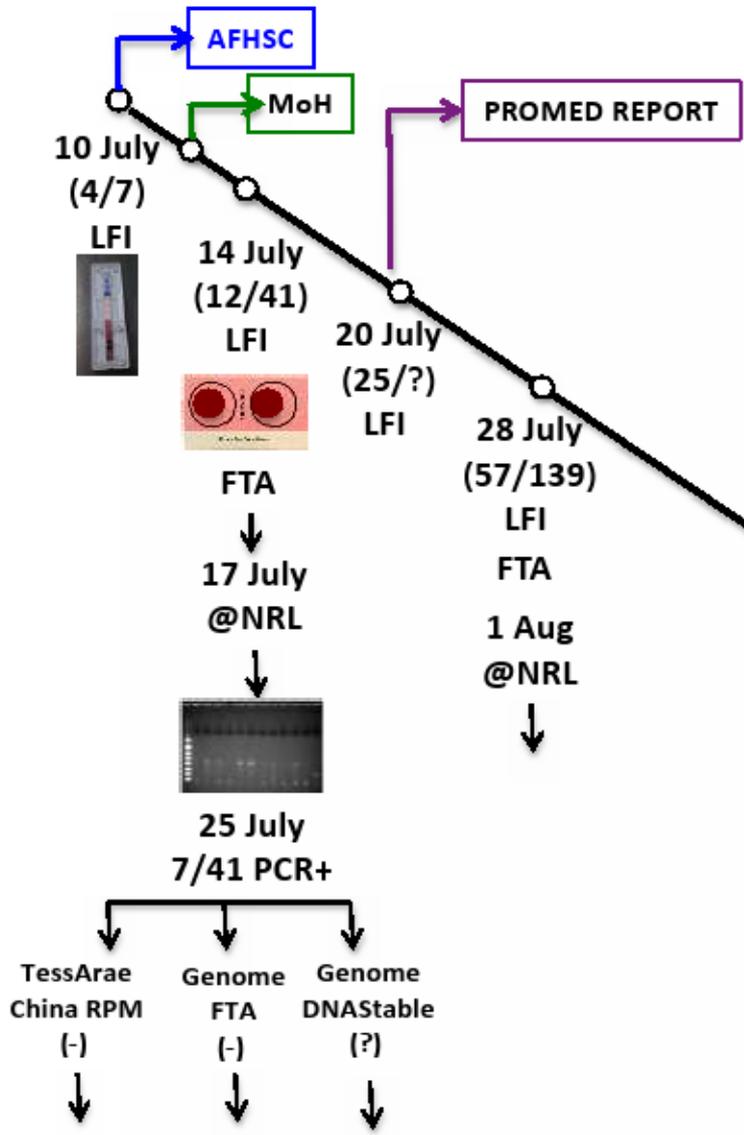
# Finding the Earliest Cases Through Biosurveillance



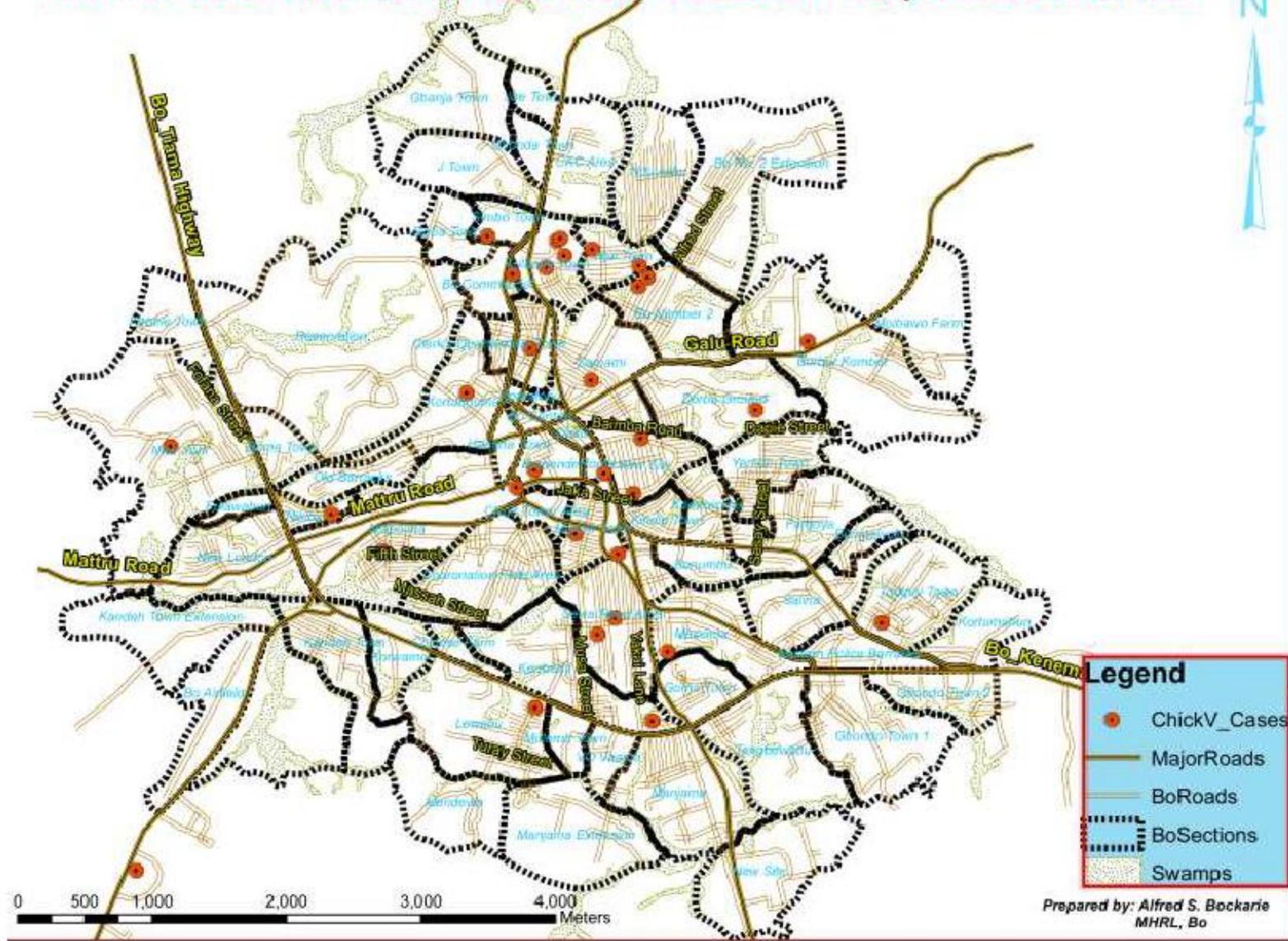
- Provide Sierra Leone District Surveillance officers with:
- Electronic reader (GPS, reads and reports lateral flow test and blood film)
  - POC Binax malaria tests
  - POC Lassa tests
  - So they can test fever patients for malaria (common) and Lassa and report patient data and test results to Kenema Reference Lab and Hospital



- Co-developed by WRAIR & Binax
- FDA-approved June 2007
- Ten-minute diagnosis
- Moderately sensitive for both *P. falciparum* and *P. vivax* malaria



# MAP OF BO SHOWING CHIKUNGUNYA CASES IN BO, SIERRA LEONE.



# COMPUTATIONAL DESIGN OF MEDICAL COUNTERMEASURES

## Novel Computational Design

- Demo to inhibit influenza hemagglutinin infective potency
- Promoting energetically-favorable clustered interactions between disembodied amino acid residues and target surface area patches to anchor de novo designed interfaces
- Incl. proxies to Negative Design: design for binding and precluding of binding to off-target molecules

DTRA CBT and DARPA Protein Design Program co-funded



# FIELD-LEVEL SAMPLE-TO-SEQUENCE

## Advancement Towards Field-Level Rapid Sequencing

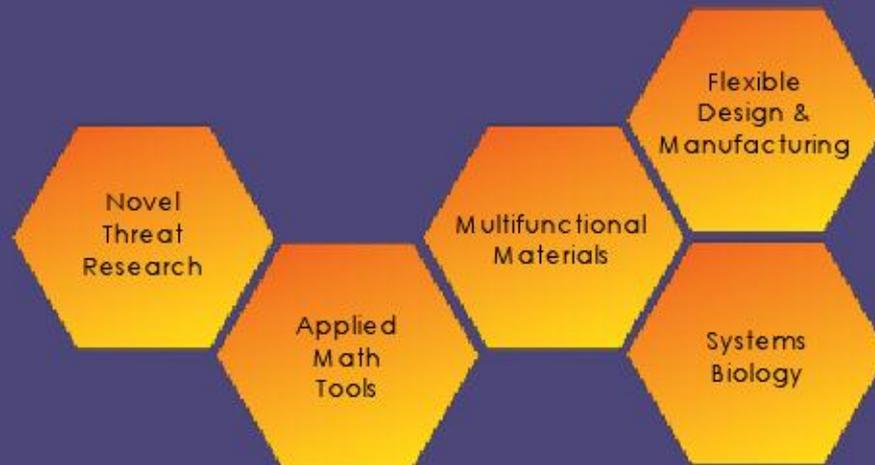
- Reduce time in field to determine if biothreat exists
- Infield biosurveillance: goal: ~1 hour sample to whole genome sequencing system (DNA & RNA)
- Processing from 24+ hours to 90 min
- Sample to sequence sensitivity to 10 bacterial cells and 100 viruses (DNA or RNA)
- PI: IBIS Biosciences/Abbot Molecular

DTRA Physical Sciences and Technology (CBT) Division funded

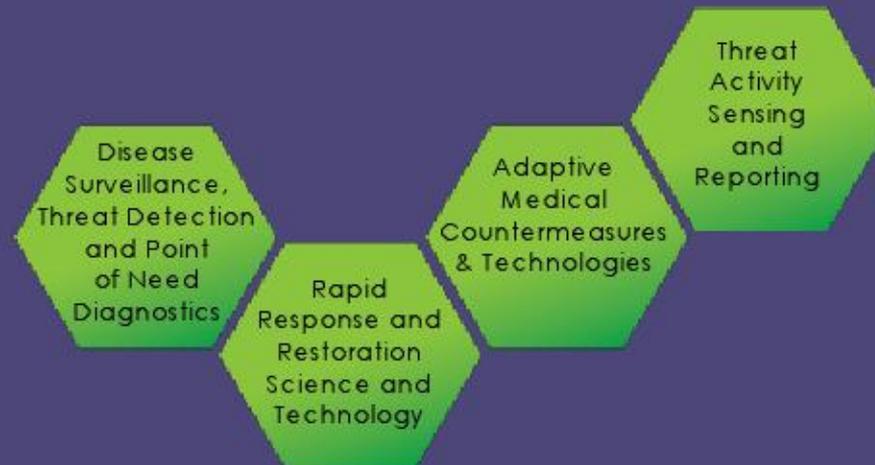


# OUR APPROACH: STRATEGIC THRUSTS AND ENABLERS

Enablers:  
Tools that help  
achieve our goals



Strategic Thrusts:  
4 Overarching Goals



Nothing game-changing is off the table



# XCEL: CLINICAL TRIALS ON SURROGATE ORGANS



Surrogate organ systems that replicates human clinical trials

Enables us to rapidly respond to new biological threats and slashes time and cost of new drug development



# WIDE AREA DECONTAMINATION OF ANTHRAX SPORES

Developing a wide are decontamination capability

This capacity will save lives in an attack and also have a host of agricultural and industrial uses



# OUR MINDSET



**Innovation  
Driven**



**Strategy  
Driven**



**Product  
Driven**



**Performance  
Driven**



**Collaboration  
Driven**



**Warfighter  
Driven**

