

# Emerging Technologies and Partnerships



**John Kools**

Advisor for Laboratory Preparedness  
Office of Public Health Preparedness and Response

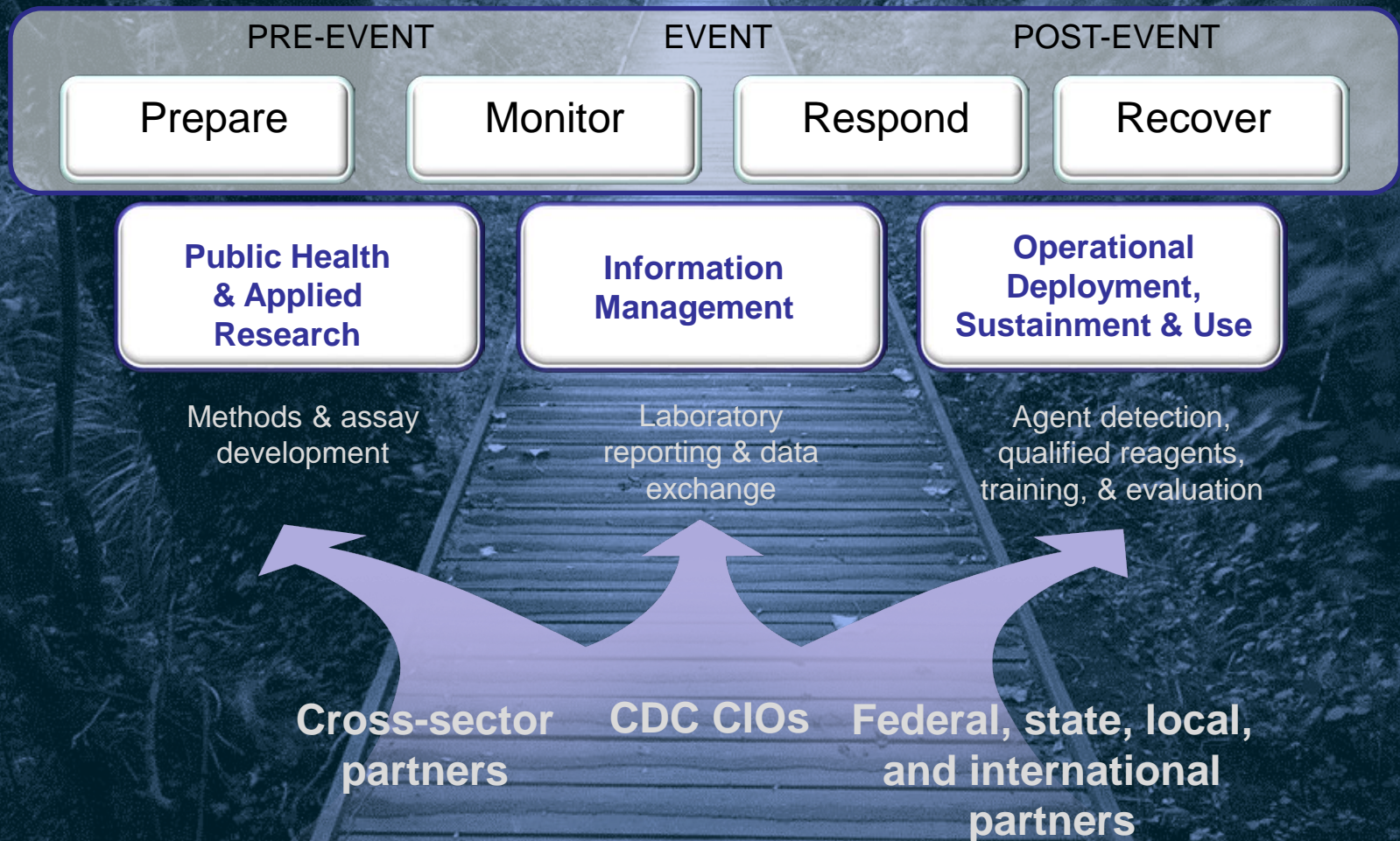
**2014 APHL Annual Meeting  
June 4, 2014**



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention

# Path Forward: PHSR Laboratory Portfolio

Investing in innovative people, processes, and products to advance CDC preparedness and response







# Emerging Technologies to Enhance Response

Exercise Control Group (ECG) Telephone and Email Service  
Simulation Call for Exercise January 27 to February 1, 2007

Position	Phone #	Email
984 Duty Officer (800 288-Contact)	800-288-7510	wood@em.gov
Health Health Organization and Member Organizations	800-832-7638	hosp@em.gov
Health and Human Services Info Call Operations/Plans and Emergency Communications Center	800-832-7638	hosp@em.gov
Health and Human Services Logistics/Pharmacy/Administration	800-832-7638	hosp@em.gov



# BOTULISM

**135** AVERAGE US  
CASES PER YEAR

**2013** FDA APPROVES  
HEPTAVALENT  
ANTITOXIN

**1M** PEOPLE KILLED  
BY 1 GRAM OF  
TOXIN



Large scale event will stress  
the public health system



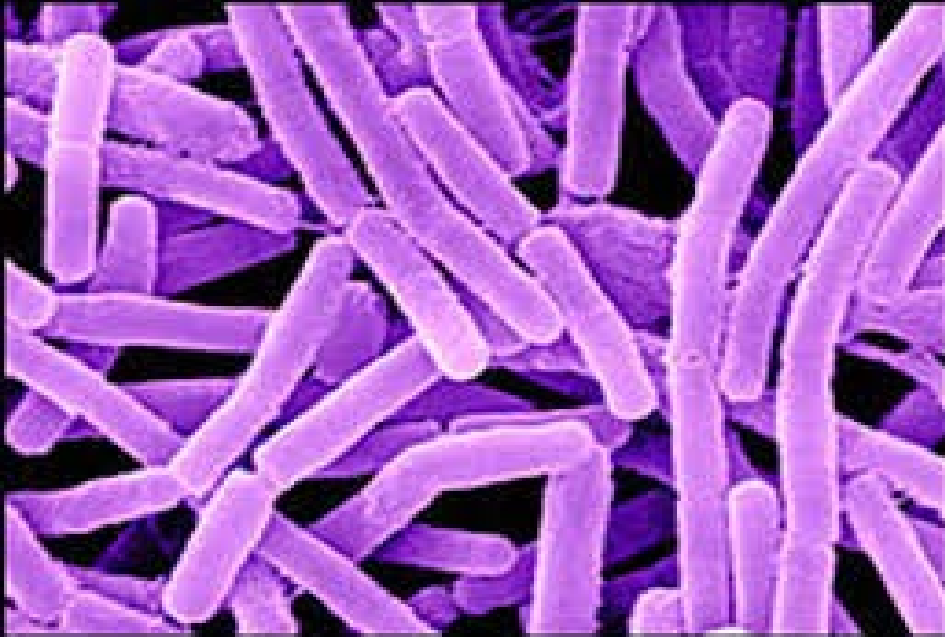
## Replacing the Mouse Bioassay

**MALDI-TOF based EndoPep MS method to detect botulism**

**Objective:** Develop an FDA-cleared, *in vitro* botulinum toxin (BoNT) activity assay to replace the mouse bioassay at US public health laboratories.

### Accomplishments:

- Developed and validated the first mass spectrometric method to rapidly detect, identify, quantify, and assess functionality all known botulinum toxin types in clinical, food and environmental samples
- Established performance specifications equivalent or better than the gold standard mouse bioassay in a high throughput method.
- Technology transfer to the CDC National Botulism Laboratory Team
- Partnering with BARDA to transition current method to a bench top MALDI-TOF instrument and deploy instrumentation and new capability



# ANTHRAX

>121,000

SAMPLES  
GENERATED  
BY 22 CASES

2001

94%  
DEATHS W/O  
TREATMENT

SNS ANTIBIOTIC  
TABLETS DELIVERED

3.7M



Large scale event will stress  
the public health system



## Are We Ready?

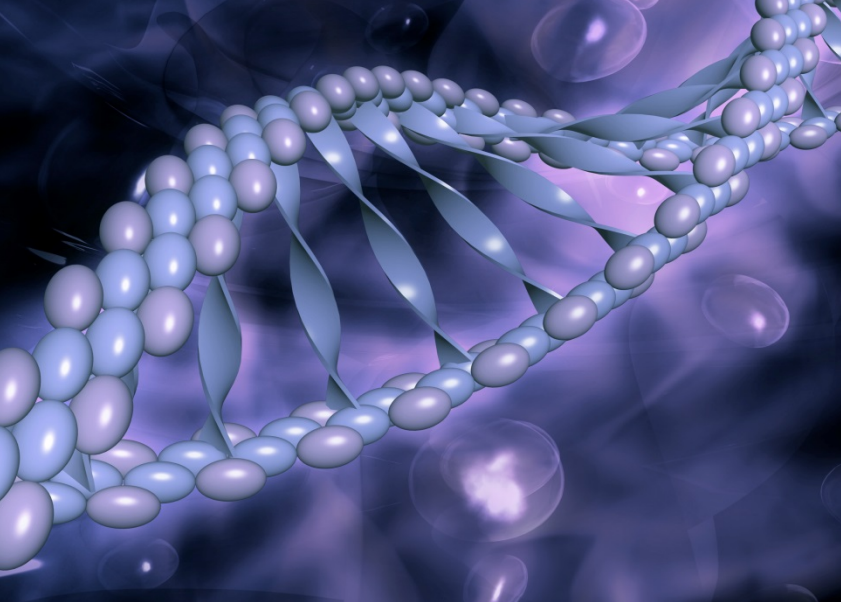
**MALDI-TOF Mass Spectrometry based  
method to detect anthrax lethal factor (LF)  
toxin activity**

**Objective:** Develop and validate an  
*in vitro*, high throughput anthrax lethal  
factor toxin activity assay

### Impact of LF Toxin Activity Measurement:

- 1<sup>st</sup> fully CLIA validated MS test for LF activity
- Culture independent
- No interference from antimicrobials and can monitor therapeutic interventions
- Earliest marker of exposure- precedes PCR, culture, and capsule detection
- Most abundant toxin, best point of care DX target
- Exquisitely sensitive LOD of 0.005 ng/ml
- High throughput makes the assay ideal for surge capacity testing (~1000 samples/ day)





# EDGE Bioinformatics

1990 2013 COST OF FLU TO BUSINESS 10.4B  
\$1B \$3K  
COST OF GENOME SEQUENCING 5 PATHOGENS RESISTANT TO ALMOST ALL DRUGS

Need for Empowering the Development of Genomics Experts

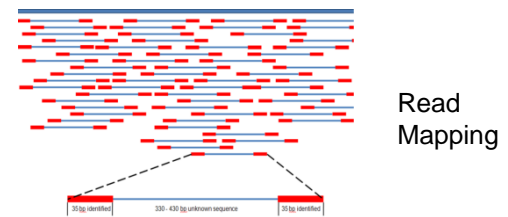
**Sequencing is not the limiting step. It's the data deluge.**

## Objective:

A turn key, intuitive solution developed by DoD and Los Alamos National Laboratory for users with modest to little bioinformatics training

## EDGE Capabilities:

- Compact, portable server: Can be used anywhere including OCONUS labs
- Extensible: Open source software with user friendly interface.
- Supports:
  - QC analysis
  - Read-mapping to a reference genome
  - Sequence assembly and annotation
- Remote Assistance: Upon request, bioinformatics specialists can log in remotely and provide support
  - Data stays on site
- Self contained: Data can be loaded onto the system, no additional connectivity necessary





# Data Integration and Visualization

2011

**48M**  
sick

**128K** hospitalized  
**3000** deaths



Improve data analytics and prepare for emerging non traditional data sources



## Improving Outbreak Investigations

**Need:** An enterprise platform to integrate, interpret, and visualize surveillance, epidemiology, and laboratory data and real time data sharing between Federal, State, and Local partners.

**Objective:** Implement an enterprise system to 1) electronically integrate diverse data sources 2) visualize outbreak data 3) secure platform for data sharing and, 4) knowledge management

### Ongoing activities:

- CDC's Outbreak Response and Prevention Branch developed the System for Enteric Disease Response, Investigation, and Coordination (SEDRIC) in collaboration with Palantir Technologies (Palo Alto, CA)
- SEDRIC utilizes commercial off-the-shelf Palantir Software
- Exploring enterprise data integration and visualization platform at CDC



# Summary

- Events are local, response must be local
- Effective cross-sector partnerships are critical for developing, validating, and deploying technologies
- Technology creates both challenges and opportunities for public health preparedness and response
  - Next generation sequencing will continue to generate large volume data sets that must be accurately analyzed
  - Newly emerging platform technologies like MALDI-TOF can utilize both threat agnostic methods (microbial ID) and threat specific assays (anthrax LF & BoNT)
  - New tools will help public health better integrate, analyze, and securely share response data at the case level leading to more rapid decision making



# Acknowledgements

## EDGE Bioinformatics

Charles Hong- DTRA

Lt. Col Rich Schoske- DTRA

Patrick Chain, PhD-LANL

LCDR Vish Mokashi- NMRC

## MALDI-TOF Anthrax Lethal Factor

Ann Boyer, PhD

Conrad Quinn, PhD

John Barr, PhD

## MALDI- TOF Botulinum Toxin

John Barr, PhD

Suzanne Kalb, PhD

Susan Maslanka, PhD

## Data Integration/Visualization

Ian Williams, PhD

Funding provided by CDC OPHPR, DoD, DHHS BARDA

# Questions?

**John Kools**

**jkools@cdc.gov 404.639.7377**

**For more information please contact Centers for Disease Control and Prevention**

1600 Clifton Road NE, Atlanta, GA 30333  
Telephone 1.800.CDC.INFO (232-4636)/TTY: 1.888.232.6348  
E-mail: [cdcinfo@cdc.gov](mailto:cdcinfo@cdc.gov) Web:<http://www.cdc.gov>

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention