



BARDA INDUSTRY DAY

ENACT

Early Notification to Act, Control, and Treat

Program Overview

Julie Schafer, PhD, MPH, MS
ENACT Acting Program Manager
October 30, 2018



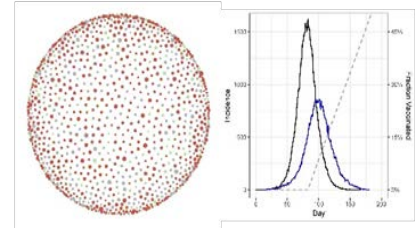
October 29-30, 2018 | Grand Hyatt • Washington, D.C.



The Critical Need for Early Information

- Infectious diseases such as influenza are a significant threat to health security
- Delayed, or no diagnosis prevents best use of medications and contributes to spread of infectious diseases in communities
- Late identification of biological and chemical exposures will delay public health response in an emergency

Innovation in technologies to allow for early information to individuals and enable early action will transform healthcare and save lives.



Traditional Healthcare Paradigm: Cost of Delays

SYMPTOMS



- Difficult to differentiate

DIAGNOSIS



- Appointment with healthcare provider
- Wait at clinic or ED

TREATMENT



- Filling prescriptions
- Many treatments work best when given early

Cost to the individual

- Illness--fever, chills, coughing
- Risk of disease progression, secondary bacterial infections
- Long wait times

Costs to the community

- Burden on healthcare system
- Loss of Productivity
- Risk of transmission and spread in the community

ENACT – Early Notification to Act, Control, and Treat



- Areas of Interest Include:
 - Novel Diagnostics, Biosensing Technologies, Wearables, and On-Person Tools
 - Health Signature Discovery and Validation
 - Indirect Indicators and Artificial Intelligence for Prediction

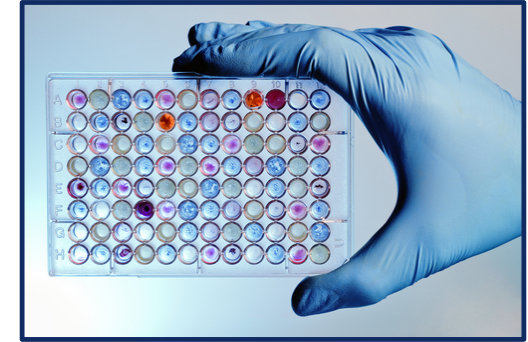
Novel Biosensing Technologies, Wearables, On-Person Tools, and Diagnostics

- Development of a next generation wearables and on-person tools toward **pre-symptomatic detection of infection and exposures**
- Minimally invasive and non-invasive technologies
- Multi-purpose devices that can be used to track and inform end user on health-related variables
- Cloud-based, advanced data analytics, and machine learning algorithms
- Diagnostics for use outside of healthcare settings, connected to systems for confirmatory diagnosis and fast provision of treatment



Health Signature Discovery and Validation

- Development of markers for health status
- Identification of those who are
 - pre-exposed
 - post-exposed pre-symptomatic
 - post-exposed symptomatic
- Prognostication of symptom onset time, duration, and future health outcomes
- Readily adapted into a panel or diagnostic technology



Indirect Indicators and Artificial Intelligence for Prediction

PRODUCTS

- *Readily available*
- *Integrated into daily life*

LEVERAGE

- *Big data analytics*
- *Artificial intelligence prediction*

PREDICT

- *Changes in healthy status*
- *Changes in behavior*
- *Potential exposure*



EnLiSense

- “Passive” eccrine sweat
- Biomarker detection
- Sensitivity maintained up to 48 hours
- Funding for process development, scale-up and proof of concept in human respiratory infection studies



SWEATSENSOR Dx Technology Highlights

Sensitivity

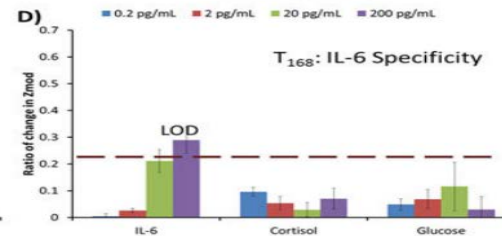
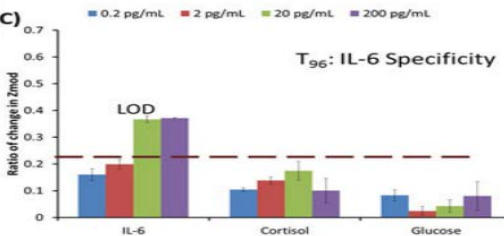
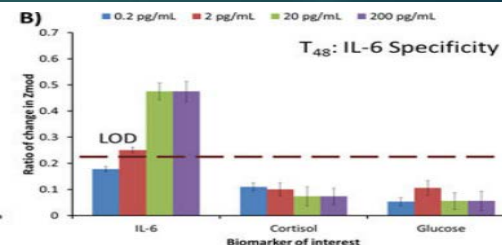
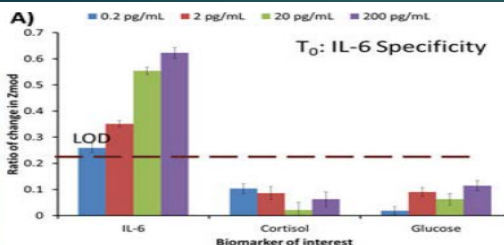
- Femto (10^{-15}) gram/mL to pico (10^{-12}) gram/mL
- Single molecule sensitivity

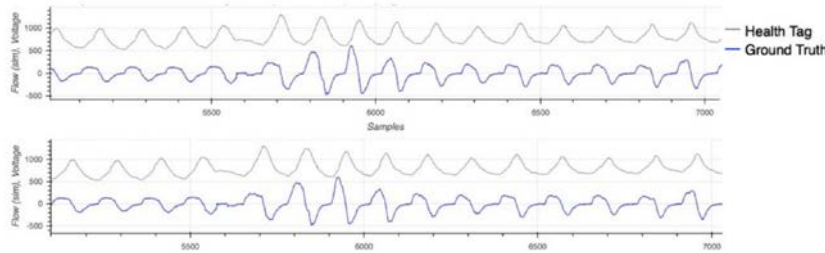
Specificity

- 99% accuracy in human sweat
- Simultaneous detection of multiple biomarkers in both low and high volumes of sweat

Response

- Testing time @ 3 minutes
- Reports concentrations of panel of biomarkers
- Dynamic, temporal monitoring up to 48 hours





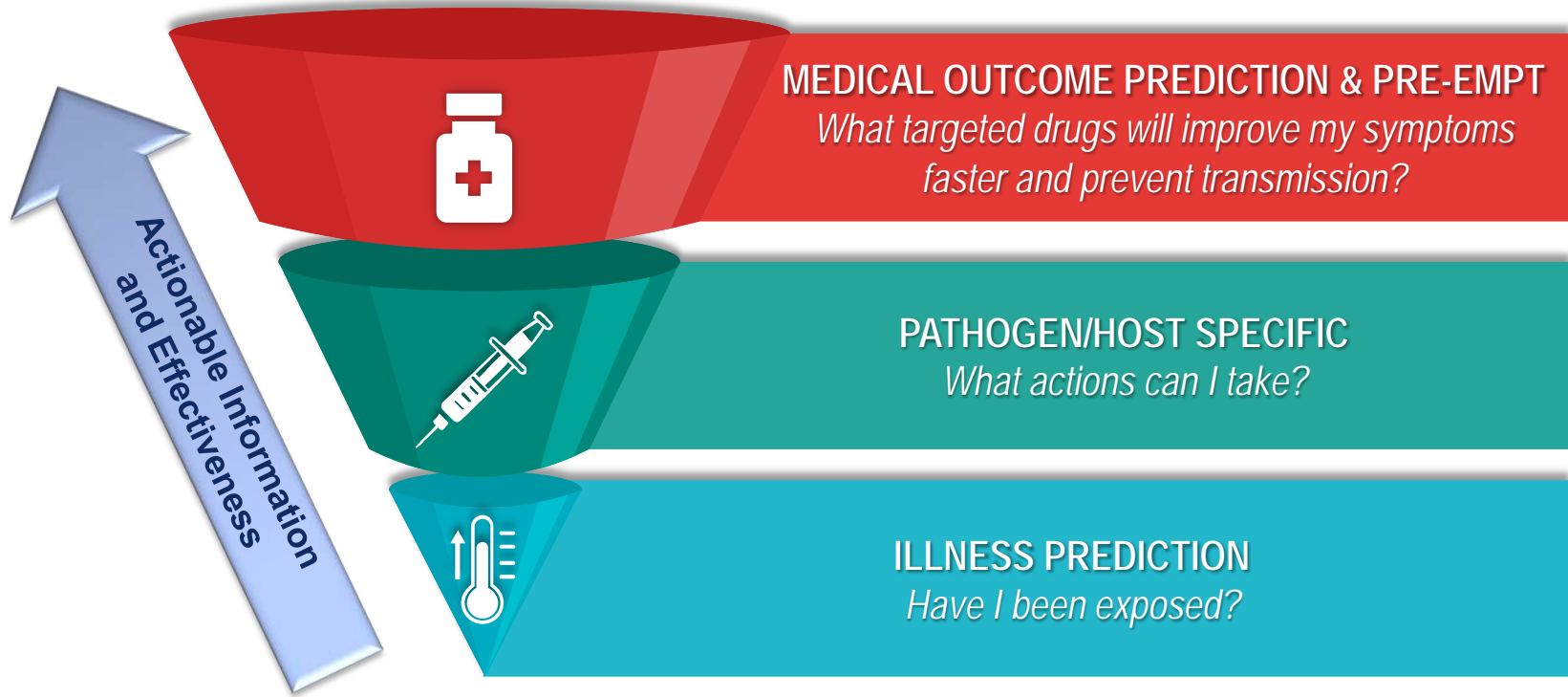
Non-invasive health monitoring

- Respiration rate tracking equivalence to medical grade monitoring
- Heart Rate and Heart Rate Variability
- Sleep/Sleep Quality
- Activity
- Stress

Leveraging the power of data analytics and science to track individual health signatures from wellness to illness

SCOPE

Part of new collaboration with DARPA. Longitudinal clinical studies during influenza season collecting health signature data. Combined with pathogen identification and next-gen sequencing to validate platform



Predicting illness and outcomes prior to symptoms and transmission