

BIIRST Distributed Diagnostics Program Overview

September 30, 2014

BioMatrix Sciences, Inc.

BIIRST Mission

Long-term:

Build a global, sustainable, distributed diagnostics model serving humanitarian needs whenever and wherever an infectious disease outbreak occurs

Immediate:

Apply our expertise and vision to help mitigate the current Ebola Viral Disease (EVD) outbreak in West Africa

What is BIIRST?

- BIIRST is the BioMatrix Infectious disease International Response Support Team
- Initiated and led by BioMatrix Sciences, Inc., focusing on the identification and commercialization of emerging technologies, including bio-diagnostics and assays
- With support from a range of experts, collaborators, and partner organizations:

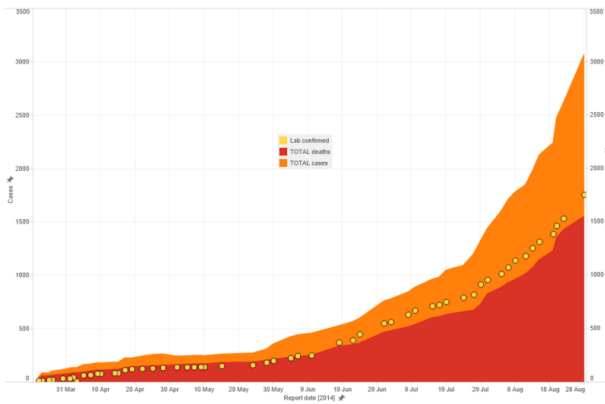


The Diagnostic Testing Problem

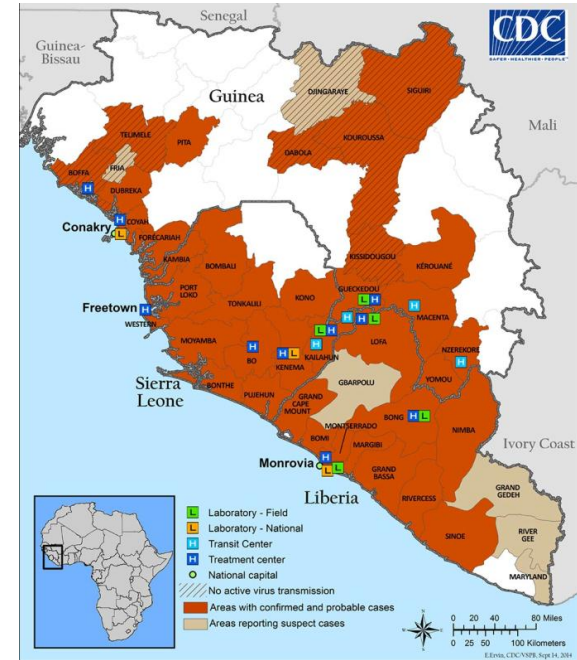
There are currently over 1,000 backlogged EVD samples waiting to be tested in Liberia alone, along with an enormous but decentralized cohort of untested at-risk individuals

“Additional decentralized labs need to be established.”

(International Medical Corps Report, 8/28/14)



Cumulative cases (orange) and deaths (red), via Ian Mackey,



Current EVD Case Count 6,574
Current EVD Confirmed (lab) Cases 3,626
Total EVD Deaths 3,091
(CDC Updated Sept. 29, 2014)

The BIIRST Solution

- Establish a rapid, distributed Ebola diagnostic & screening capability in Sierra Leone that can be readily replicated in other nations facing Ebola and other viral outbreaks
 - Supply an end-to-end solution
 - Mobile labs and “labs-in-a-backpack” equipped with fast PCR for on-the-spot screening and diagnosis
 - Wireless/satellite communications for Epi data collection and dissemination
 - Base Lab with sequencing capability and reach back to medical researchers
 - Conduct initial operations (6 weeks) then train local/NGO partners to take over and mentor them through the transition
 - Establish ongoing oversight and supply chain management and funding streams to ensure assays, lab supplies, and equipment spares are available as /when needed

6-Month Program Outline

- Phase 0. Readiness (Weeks 1-4, Pacing Item is Availability of Lyophilized Assays)**
- Confirm arrangements, on-the-ground conditions
 - Assay validation on 2 platforms (SwRI & DoD USAMRIID)
 - Sample Preparation methodology evaluation at SwRI)
- Phase 1. Mobile Testing & Epi Data Collection System - Set-up & Initial Operations (Weeks 5-10)**
- 1.A. Relocatable/Mobile Lab
 - 1.B. Base Lab for support & sample sequencing
 - 1.C. Epidemiological & Sequencing Data Collection/Reach-back
- Phase 2. Training Local/NGO Partners to Assume Operations (Weeks 9-10)**
- Phase 3. Operations by Local/NGO Partners (Weeks 11-24)**
- Phase 4. Equip & Field Distributed (Handheld) Diagnostics Teams (Weeks 11-24)**

Anticipated Outcomes

- **Speed diagnosis** – *Reduce wait time for results from days to less than 1 hour, and help clear testing backlog*
- **Focus Treatment Resources** – *Rapid diagnosis will set up and speed isolation and treatment of infected individuals*
- **Provide Diagnosis Capability Anywhere** – *Labs/mobile teams travel to remote sites, no need to transport samples for processing*
- **Improve Epidemiological Picture** – *Labs/mobile teams can collect and automatically feed data to Base Lab and researchers*
- **Aid therapeutic Development** – *Provide sequencing and meta data to track evolution of virus during outbreak to aid diagnostic and therapeutic development*
- **Create a Sustainable Self-Help Capability for Future Viral Outbreaks** – *Training, mentoring, leave-behind equipment and assured supply chain*

Program Challenges

- Gain endorsement/acceptance by WHO for operations in-country – work with/through local NGOs
- Obtain needed approvals for use of the proposed PrimerDesign assays and/or access to currently approved assays in sufficient quantity
- Demonstrate gold-standard qPCR performance
- Provide an additional layer of security & tracking for personnel in remote and hostile environments
- Provide a communication infrastructure to enable reliable and critical data transmission in extremely remote locations

Planned Concept of Operations



Manage the Logistics Challenges

- *Supply*
- *Communications*
- *Transportation*
- *Security*
- *Access*
- *Power*

Training/Proficiency

- *PPE*
- *Sample prep*
- *Testing*
- *Reporting*
- *“Train the trainer”*

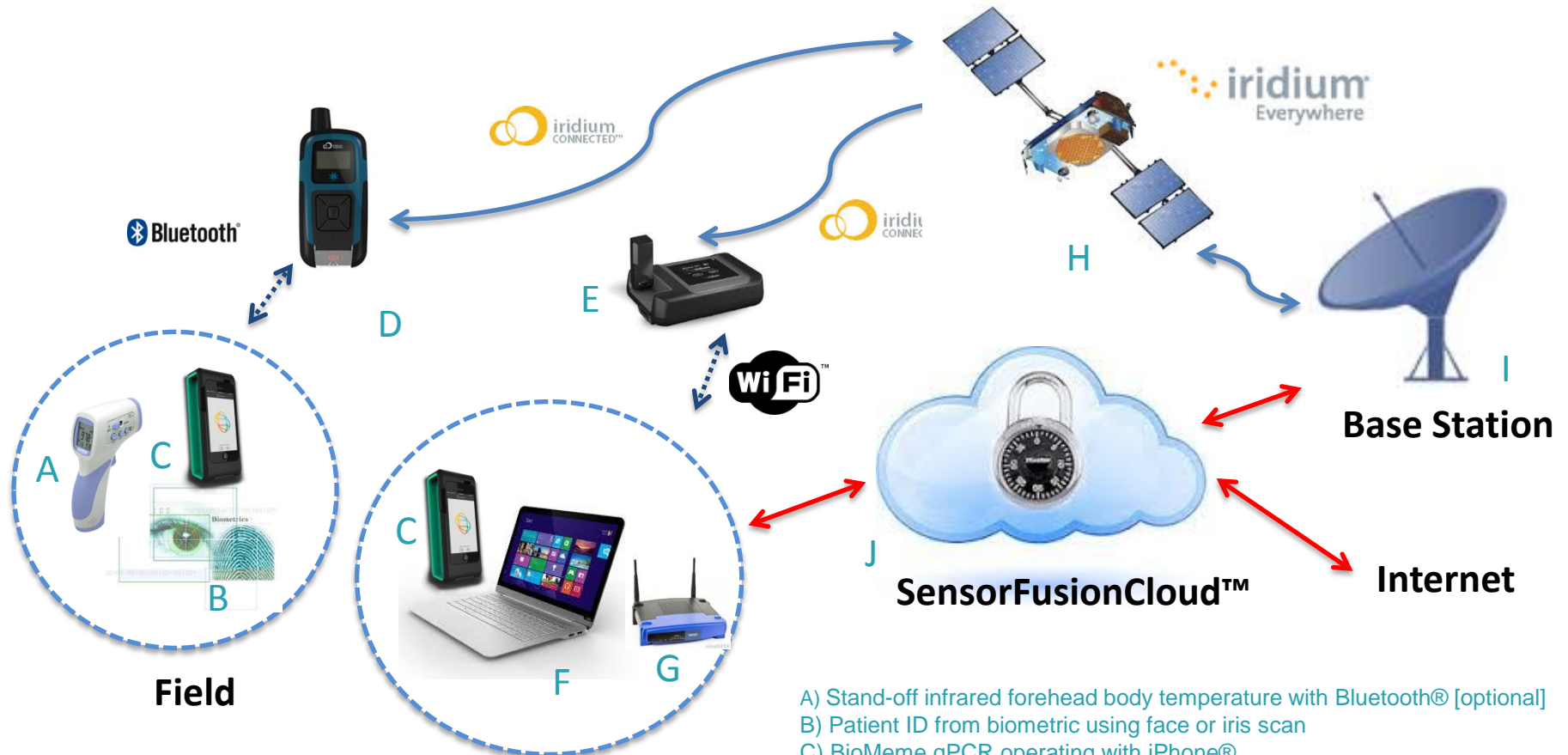
Operations

- *Technical/ logistics transition*
- *2 or 3-person functional teams*
- *GPS/meta data capture*
- *Barcode samples*
- *Reporting*
- *Collaboration and reach back*

Distributed Diagnostics Concept of Operations

- Team travels to remote location(s) with Mobile Lab or Lab-in-a-Backpack)
 - 1) Screen for elevated body temperature (contactless IR forehead)
 - 2) Acquire biometric to create patient ID (contactless face or iris)
 - 3) Measure body temperature (contactless IR forehead)
 - 4) Record Epi data
 - 5) Take sample from patient
 - 6) Run qPCR test on the spot
 - 7) Transmit Priority 1 data to Base Lab via satellite
- Return to Base Lab
 - 1) Selected samples sequenced
 - 2) Sequencing data & meta data transmitted over high bandwidth connection
 - 3) Epi/diagnostic data view via web interface and/or actionable information transmitted to land, web or satellite devices
 - 4) Decontaminate gear, dispose of medical waste
 - 5) Check all equipment and re-stock Mobile Lab/Lab-in-a-Backpack for next sortie

Implementation Schema



KEY

- A) Stand-off infrared forehead body temperature with Bluetooth® [optional]
- B) Patient ID from biometric using face or iris scan
- C) BioMeme qPCR operating with iPhone®,
- D) Zenzium tracker/communication/gateway device employing Iridium SBM
- E) High bandwidth *Iridium Go* gateway [optional]
- F) Laptop / Desktop [optional]
- G) WiFi / Ethernet router for terrestrial connectivity
- H) Iridium satellite constellation (66 low earth orbit LEO)
- I) Iridium base station (served by Iridium)
- J) Zenzium secure SensorFusionCloud™

Keys to Successful Implementation

- **Expertise** – *Scientific, technical, and logistics for operational bio-surveillance mission*
- **Coordination** – *Local, regional, national, NGOs, corporations and governments*
- **Technology** – *Complete advanced distributed diagnostic capabilities – Emergency and Research Use Only (RUO), screening applications leading to full global clinical approvals*
- **Logistics** - *Fast supply chain activation, coordination and distribution*
- **Sustainment** - *Resources identified for personnel equipment, diagnostics, and supplies*

Team Capabilities

- Key personnel with expertise/experience in all aspects of proposed program
- Hands-on experience working in the field in West Africa
- Expert virologists and labs on call
- Established working relationships with key equipment and assay suppliers
- Ability to leverage resources/liaison with DoD agencies
- Strong personal and team commitment to making a difference

Projected Partners

- Primer Design, Ltd., UK – *Ebola/Zaire assay*
- Scripps Institute (TSRI) – *Ollmann Sapphire Lab, African disease therapeutics and advanced diagnostics*
- Biomeme Inc. – *handheld qPCR diagnostics*
- Southwest Research Institute[®] (SwRI[®]) – *assay and sample prep validation*
- Texas Biomedical Research Institute – *systems qualification and live agent testing*
- Zenziun, Inc. – *vital signs sensors, SatCom, Big data & predictive analytics*

Key Personnel and Advisors

- **Dr. Evan Skowronski, Chief Scientific Officer at TMG Biosciences**
 - Extensive experience in environmental microbiology, microbial forensics/detection, and assay development from genomics-based target selection to formal validation.
 - Former Division Chief of Biosciences at the Edgewood Chemical Biological Center, overseeing a staff of 100 scientists with a \$40M budget
 - Sequencing Manager of DOE's genomics laboratory at LLNL and later assay development lead.
 - Co-winner of the R&D100 award for the development of the deployable surveillance laboratory developed for the Capitol Region Anthrax incident.
- **Dr. Lisa Lott, President and Chief Science Officer at Goliad Scientific**
 - 20 years experience in the field of microbiological and molecular research, public health surveillance, and epidemiology.
 - Chief Science Officer, Goliad Scientific LLC supporting Force Health Protection and local public health communities in the areas of biosurveillance and molecular pathogen identification, transmission, incubation, prevention.
 - Former Senior Scientist at the Air Force Center for Advanced Molecular Detection
 - Managed multiple high priority multi-million dollar R&D and medical contracts including the \$50M Medical and Scientific Support Services Contract for the Centers for Disease Control and Prevention (CDC) coordinating international medical, scientific and epidemiological support services
- **Jeff Brodeur, Subject Matter Expert at Countering WMD Solutions, LLC**
 - 29 year veteran of the Army Chemical Corps responding to CBRN incidents at the tactical through strategic levels
 - Former Assistant Commandant for the US Army CBRN school responsible for the training-equipping-organizing for the 20,000 Soldiers missioned to conduct wide area hazard assessment.
 - Senior CBRN officer at US Army Central during the Arab Spring when many of the largest WMD inventories in the world were least secure and most likely for employment
 - Experienced planner, and programmer of resources and training to develop the emergency management response of partner nations in the following regions: Middle East, Pacific Rim, Europe, and the United States and associated territories.

Key Personnel and Advisors, cont.

- Ross I. Donaldson, MD, MPH, UCLA Schools of Medicine and Public Health
 - Director of the Emergency Medicine Global Health Program at the Harbor-UCLA Medical Center
 - Internationally recognized expert on the global provision of emergency and disaster care, author of *The Lassa Ward*, a memoir about international aid work, and creator of the Global Emergency Medicine Wiki used by over 20,000 medical professionals worldwide.
 - Has worked around the globe, in Africa, Asia, the Caribbean, Europe, Latin America, and the Middle East, having received and managed over \$15 million dollars of grants for emergency health care system strengthening worldwide.
- Dr. Erica Ollmann Saphire, Professor of Immunology and Microbial Science, The Scripps Research Institute
 - Leads laboratory investigating how compact RNA viruses like Ebola, Marburg and Lassa viruses manifest pathogenesis, and identifies key cracks in their armor that can be exploited for diagnostics, therapeutics, and vaccines.
 - Currently mapping the molecular structure of Ebola and its antibodies, working with colleagues in seven countries
 - Established the first biologically supported model of Ebola assembly, which unequivocally demonstrate that the protein folds into distinct structures for separate biological functions, opening the door to a novel class of antivirals against structural inter-conversion.
 - Director of the Viral Hemorrhagic Fever Immunotherapeutic Consortium which united the field into a single force to understand and provide antibody therapeutics against Ebola, Marburg, Lassa and other viruses.
- Jay Creutz, VP Program Management at BioMatrix Sciences
 - Over 25 years experience in systems integration, management of technology-based programs, and program development in the U.S. and internationally.
 - Project Manager for \$50M security system for the 2002 Winter Olympics, and Liaison Officer for DTRA's Consequence Assessment Center conducting WMD what-if analyses including bio-threats. Received personal medals of commendation from the FBI and the multi-agency Utah Public Safety Command.
 - Deputy PM and System Architect for \$300M security system for the 2004 Summer Olympics in Greece.

Seeking

- NGO Partner(s) with in-country support network in the affected areas
- Funding
- Access to military equipment, transport, expertise in order to reduce costs
- Means of quickly acquiring current approved Ebola assays in sufficient quantities
 - Primer Design test kits will not be available in production quantities until mid-November and are not yet WHO approved
 - Mobile lab operations could begin up to 3 weeks earlier if we had an alternate source

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