



Outbreak Readiness and Response

integrumsci.com

Developed as a direct response to the lessons we learned when responding to critical infectious disease outbreaks

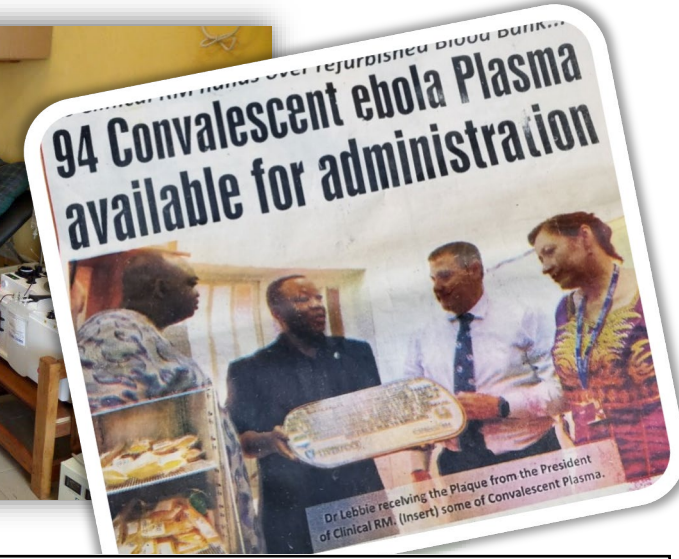
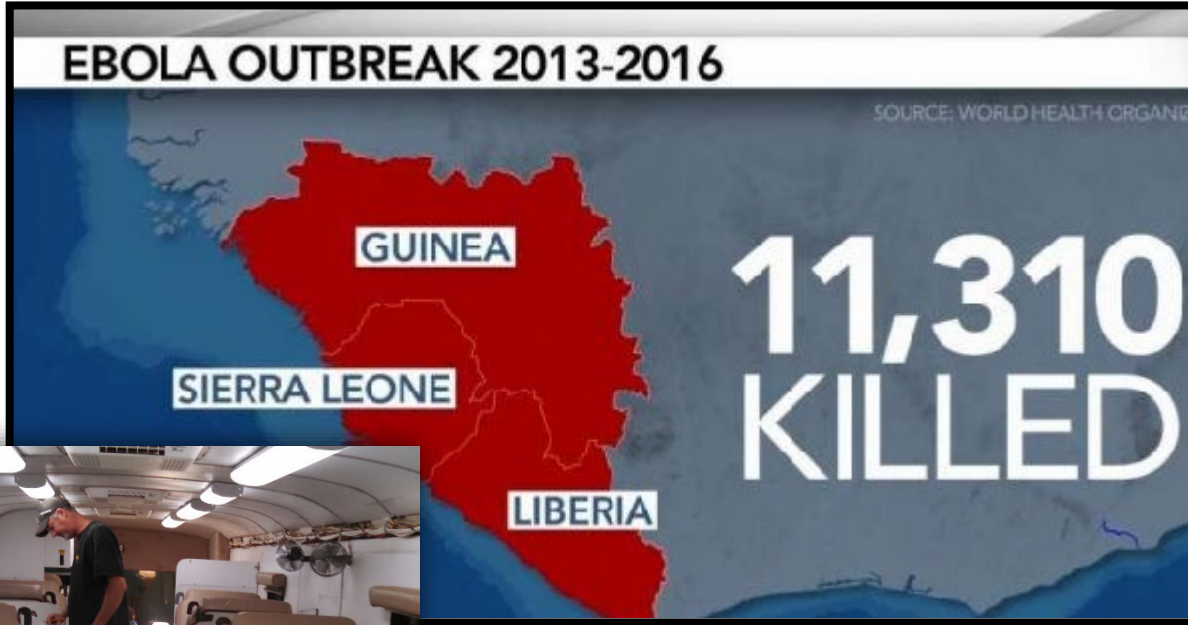
OUR VISION

To *reduce the impact* of infectious disease threats, especially in the *most vulnerable regions of the world*

OUR MISSION

To *improve the effectiveness* of global and local clinical research initiatives by promoting *prevention, preparation, and awareness*

*Developed as a direct response to the lessons learned
responding to real pandemic outbreaks*



Infectious Disease Scientific Advisory Board

World leaders in infectious disease field responsive research, specialty vehicle design and manufacturing, and international logistics – International *“GO TO”* Team for COVID Response



**Calum Semple, MD,
PhD**



John Dye, PhD



**Julius Lutwama,
PhD**



David Hoover, MD



Kartik Chandran, PhD



Cathy Bansbach, PhD



Keyur Patel, MD, PhD



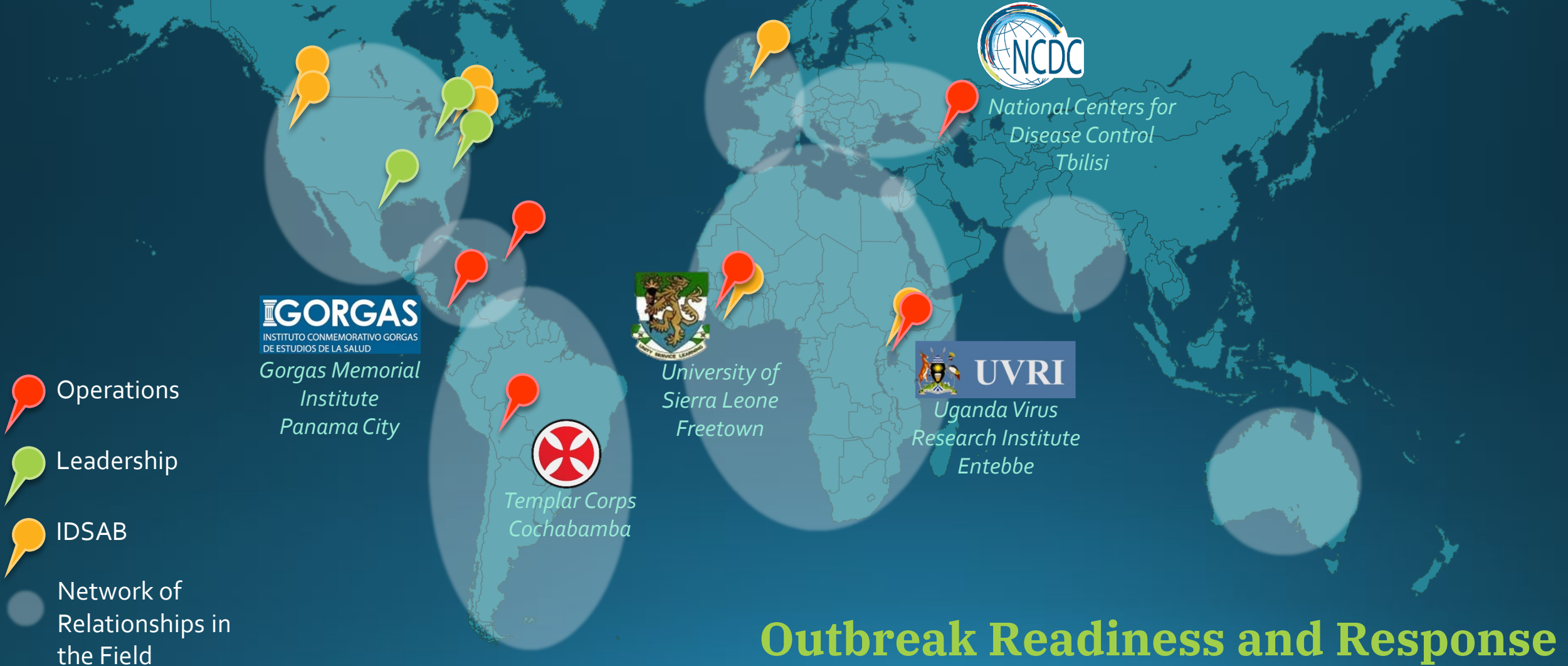
**Kimmie Weeks, Hon.
PhD**



Brad Matthews



Philip Maxson



OUR APPROACH



Prevention

- Clinical trials
- Classic and Adaptive study design
- Protocol Design, Project Management, Monitoring



Surveillance

- Global surveillance through network of thought leaders and footprint in the ID hotspots
- Ground truth assessment
- Sample collection, biobanking & shipping



Recovery

- Support to survivor networks
- Legacy – Leave on good terms
- The best resource for the future that builds resilience



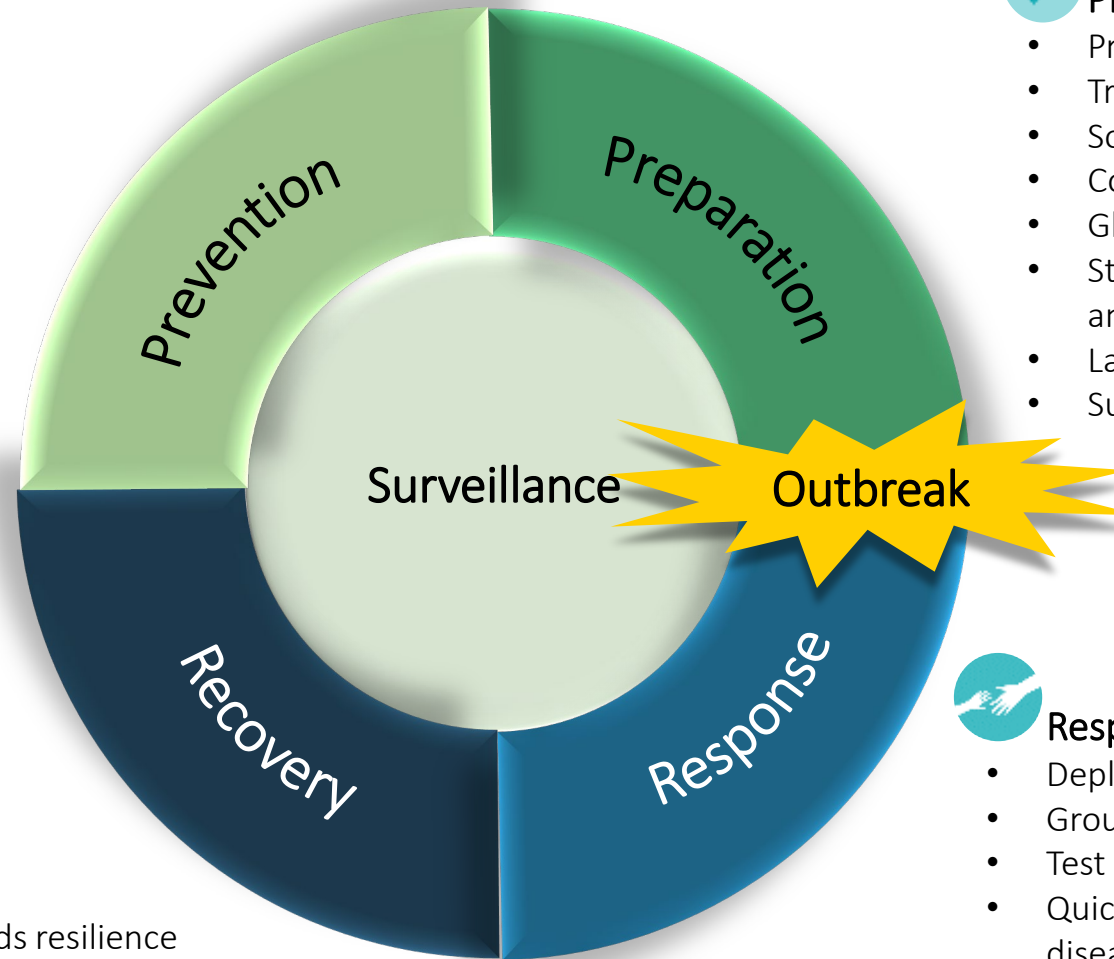
Preparation

- Pre-negotiated global agreements
- Training & Education
- Social & Anthropological Expertise
- Country-specific regulatory support
- Global Infrastructure Development
- Standardized protocols, study documents, and communication lines
- Lab assessments and strengthening
- Supply chain and logistics support



Response

- Deployment support
- Ground truth assessment
- Test & treat with mobile labs
- Quick mobilization of global infectious disease experts, & trained on-the-ground professionals
- Networked with NGOs & WHO





INTEGRUM Scientific OUR SERVICES

- Develop and implement clinical research in hot spots for infectious disease outbreaks
- Protocol design support
- Project Management
- Clinical Monitoring with experienced, in-country Clinical Research Associates
- Site feasibility assessments and site qualification visits
- Subject recruitment and retention support
- Infrastructure development support
- Cold chain support
- Lab Assessments
- Lab Supply & Equipment Procurement



BILL &
MELINDA
GATES
foundation



| Project Focus | Global Region |
|-------------------------------------------------------------------------------------------|------------------------------------------|
| <i>Chikungunya Vaccine Phase 2a Study</i> | <i>Puerto Rico</i> |
| <i>Atropine Study</i> | <i>United States</i> |
| <i>Marburg Virus Disease & Rift Valley Fever Sample Collection</i> | <i>Uganda</i> |
| <i>Venezuelan Equine Encephalitis Sample Collection</i> | <i>Panama</i> |
| <i>Machupo Virus Sample Collection</i> | <i>Bolivia</i> |
| <i>Crimean Congo Hemorrhagic Fever Virus and Old World Hantaviruses Sample Collection</i> | <i>Republic of Georgia</i> |
| <i>Lassa Mammarenavirus Sample Collection</i> | <i>Sierra Leone</i> |
| <i>Measles, Mumps, & Rubella Vaccine Study</i> | <i>Colombia & Dominican Republic</i> |
| <i>COVID Laboratory Supply & Equipment Procurement</i> | <i>Throughout Africa</i> |

LABORATORY SUPPLY PROCUREMENT & LOGISTICS

- Expertise in global logistics, especially to hard to reach locations
- Continuously vetting new vendor sources for better pricing and more efficient timelines for delivery
- Lower costs secured through bulk purchasing
- Transparent reporting for better shipping and financial tracking



Clinical Trial Support from Preclinical to Phase IV Studies

Bio-Analytical
Services*

Clinical Monitoring

Clinical Data
Management*

Cold Chain Support

Data Safety
Monitoring Boards

Independent Medical
Monitoring

Infrastructure
Development
Support

Medical Writing,
Statistical Analysis, &
Reporting*

Program and Project
Management

Protocol
Development &
Review

Quality Management
& Compliance

Regulatory Support,
Guidance &
Submission*

Risk Management

Safety Oversight &
Pharmacovigilance*

Site Selection,
Qualification &
Management

Subject Recruitment
& Retention

Supply & Equipment
Procurement &
Logistics
Management

Training and
Education
(GCP, GLP, GMP)

Vaccine Research &
Sample Collection for
Standards
Development

** Integrum teams with industry partners to maximize
efficiencies while providing best in class service*

Project Management Approach

Contract Management

Change Control

Communications Management

Schedule Management

Deliverables Management

Human Resources Management

Refinement of
operations

Evaluation of
customer
requirements

Thorough
evaluation and
QC

Expert staffing

Transparent
communication

| Customer | Project Name | Project Location | Services Provided |
|--------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The Geneva Foundation | Phase 2a Study of a Measles-Vectored Live Attenuated Chikungunya Vaccine in a Previously Epidemic Area in Adults 21-65 Years of Age | <i>Puerto Rico</i> | Integrum provides clinical research support <ul style="list-style-type: none">clinical trial management and study monitoringoversight of data management, serious adverse event reporting, and statistical analysis |
| Rho | Randomized, 3-Way Crossover Study to Assess the Bioavailability and PK of a Single Dose of Atropine Administered Sublingually | <i>United States</i> | Integrum provided an independent medical monitor for a BARDA Atropine study in healthy adult volunteers |
| USAMRIID | Development of Novel Monoclonal Antibodies and Longitudinal Study of Immune Responses Using Serum and PBMC's of Infectious Disease Survivors | <i>Uganda, Panama, Bolivia, Georgia, Sierra Leone</i> | Integrum provides project management, quality assurance, and database development and maintenance to facilitate operations with partners in country to identify and track survivors of Marburg virus disease (MVD) in Uganda, Venezuelan equine encephalitis (VEE) in Panama, Machupo virus (MACV) in Bolivia, Crimean Congo Hemorrhagic Fever Virus (CCHFV) and Old World Hantaviruses in the Republic of Georgia and Lassa Mammarenavirus (LASV) in Sierra Leone . |
| Emergent Biosolutions | Consultation | <i>Global</i> | Integrum’s IDSAB provides consultation on a wide portfolio to help our client improve their science and launch new solutions worldwide. |
| The Bill & Melinda Gates Foundation | COVID-19 Illumina Africa CDC sequencing support | <i>Africa CDC & ASLM</i> | Integrum provides procurement and distribution of key commodities for a dozen African labs through the Africa CDC as well as the African Society for Laboratory Medicine. |
| Coalition for Epidemic Preparedness Innovations (CEPI) | Rift Valley Fever Project | <i>Uganda</i> | Integrum collects and provides to the National Institute for Biological Standards and Control (NIBSC) serum material from patients in regions across Uganda who have recovered from Rift Valley Fever (RVF) and Marburg virus disease (MVD) . This will enable NIBSC to compose serum panels and an International Antibody Standard for RVF and MVD (IS) for use by vaccine developers worldwide. |
| TRI | CRO Services for a Clinical Trial of Measles, Mumps, Rubella Vaccine and Yellow Fever Vaccine Co-administration | <i>Colombia, Dominican Republic</i> | Integrum provides Project Management and Quality Assurance for this PATH study for co-administration of a Measles, Mumps, and Rubella (MMR) Vaccine with a Yellow Fever (YF) Vaccine in children ages 12-14 months of age. |
| African Society of Laboratory Medicine | BMGF Laboratory Network | <i>Countries throughout Africa</i> | Integrum provides project management, supply procurement, and to provide genomic sequencing reagents and supplies to Africa CDC members. |

NEXT GENERATION MOBILE LABS

Fully customizable

Rapidly deployable

Highest quality equipment

Rugged dependability

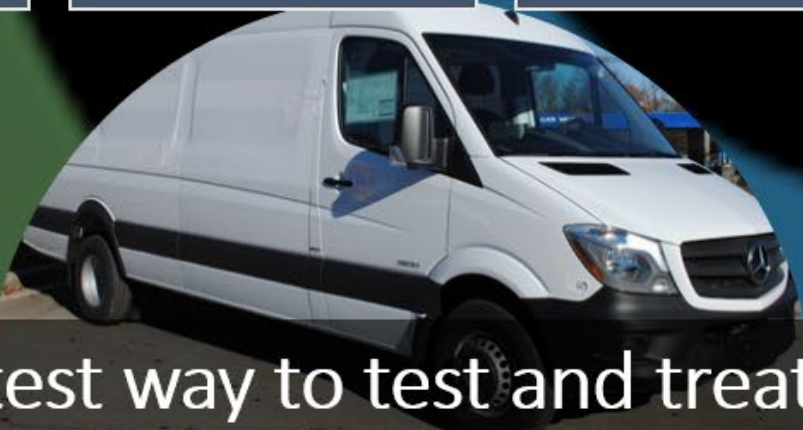
Power redundancies

24/7 support

Trained staff

Expert Project Management with dedicated Quality Assurance/Control

Backed by leading global experts



The fastest way to test and treat on site in challenging environments



Outbreak Readiness and Response

integrumsci.com

Or contact us via email at:

Joe.Sgherza@IntegrumSci.com or

Vicki.Chilton@IntegrumSci.com