Presentation Overview

- Discuss Areas of Emphasis for Clinical Research Response
- Review Operational Table of Contents for Nipah
- Discuss Related Operations Management Strategies
  - Partnership Management
  - Strategy Management
Keys to Successful Clinical Research Response

Science

Operations  Strategy
Keys to Successful Clinical Research Response

- Science
- Operations
- Strategy

Diagram:
- Science
- Operations ↔ Strategy
Nipah Response- Science and Operations

Monitoring:
- Capacity Assessment
- Protocol Monitoring Plan
- Safety Monitoring Plan

Regulatory & Ethics:
- Local Capacity Assessment
- IND & Local Reg Submissions
- IRB submissions
- Consent Form

Bio-statistics:
- Data Analysis Plan
- DSMB Reporting

Pharmacy:
- Capacity Assessment
- Drug Storage
- Cold-chain management
- Supplies
- Pharmacy staff training

Data Management:
- Capacity/Resource Assessment
- Case Report Forms
- Data Management System
- Data Table / Reports

Site Management:
- Capacity Assessment
- Patient Flow
- Site Staff Training

Social Mobilization:
- Capacity Assessment / and Local Situation Analysis
- SMC plan

Laboratory:
- Capacity Assessment
- Supplies
- Equipment
- Lab staff training

Logistics:
- Visa invitation
- Visa processing
- Travel
**Organizational Structure**
**Liberian - US Joint Clinical Research Partnership**

**Minister of Health and Social Welfare**
**US Ambassador**
Liberia: Dr. Walter T. Gwenigale
US: Ambassador Malac

**Executive Committee (EC)**
Liberia: Drs. Francis Kateh, Yah Zolia, Emmet Dennis
US: Drs. Cliff Lane, Frank Mahoney/Kevin DeCock

**External Advisory Committee**

**Operations Headquarters**
**Chief Operations Officers**
Liberia: Wissed Si Njoh, Julia Lysander, Jemee Tegli
US: Laura McNay, Gregg Larson

**Social Mobilization and Communication**
Liberia: Mosoka Fallah; Kalipha Bility
US: Libby Higgs

**Psychosocial**
Liberia: Kalipha Bility; Janice Cooper
US: Libby Higgs

**Monitoring & Evaluation**
Liberia: Eugene Dolopei; Wissed Si Njoh
US: Susan Vogel

**Data and Information Technology**
Liberia: Luke Bawo; Saye Baowo
US: Jim Neaton

**Protocol Principal Investigators**
Vaccine: Stephen B. Kennedy; Clifford Lane
Treatment: Moses Massquoi; Richard Davey

**Pharmacy**
Liberia: Bryan Johnson; Moses Massquoi
US: Jerry Pierson

**Site Development**
Liberia: Wissed Si Njoh; Julia Lysander
US: Risa Eckes

**Site Management**
Liberia: Saye Baowo; Garfee Williams
US: Risa Eckes

**Laboratory**
Liberia: Joel Jones; Fatalma Bolay
US: Beth Baseler; Marie Hoover

**Training**
Liberia: Garfee Williams; Julia Lysander
US: Mary Smolskis; Margaret Sherman

**Regulatory and Ethics**
Liberia: Jemee Tegli; Fatorma Bolay
US: John Tierney
Nipah RCT Protocol Standard Operating Procedures - Table of Contents

I. Introduction to the Standard of Procedures
   a. Purpose

II. Informed Consent Process
   a. Documentation of Consent

III. General Hospital and Protocol Implementation
   a. Schedule of Events
      i. Screening and Enrollment
         1. Inclusion/Exclusion Criteria review
         2. Clinical assessment, neurologic assessment
            i. Contact information/Demographics
            ii. Medical History/Physical Examination/ Glasgow Coma Scale
         3. Clinical labs
         4. Research labs/NiV RT-PCR
         5. Randomization
   b. Study Agent Administration
IV. Pharmacy:

a. Storage, Handling and Temperature Monitoring of Nipah Virus Study Agents
   i. m102.4
      1. Storage and Temperature Monitoring of m102.4
      2. Preparation
      3. Transport and Return
      4. Disposal of unused investigational IV bags
      5. Pharmacy Manual
      6. Pharmacy procedure
      7. Investigational Product Accountability Log
      8. Pharmacy Training and Delegation Log

V. Safety Assessment and Reporting

a. Reactogenicity management, anaphylaxis and adverse event management
b. Needle stick procedure for clinical staff
VI. Data Management
   a. Source Documents and Forms Completion
      i. Evaluation and procedure notes and reports
      ii. Agent Administration Form - Day 1 and Day 2
      iii. Follow-up Daily assessment and Optimized Supportive Care
      iv. Discharge Form
      v. Day 28 and Day 56
     vi. Missed Day 28 and Day 56
     vii. Optional Day 90 and Day 180
     viii. Concomitant medications and Adverse Events
      ix. Paper and electronic CRF completion
   b. Event Forms Completion
      i. Death
      ii. Pregnancy Outcome
      iii. Protocol Deviation
   c. Reporting Serious Adverse Events (SAEs)

VII. Specimen and Laboratory Management
   a. Specimen collection, handling and storage
   b. Specimen processing
Nipah RCT Protocol Standard Operating Procedures- Table of Contents

VIII. Regulatory
   a. Regulatory and Regulatory Bodies
      i. ICMR/India
   b. Protection of Human Subjects
   c. Essential Documents
   d. Required Documents
   e. Document Maintenance

IX. Site Quality Management Plans

X. Site Monitoring
   a. Site Preparation
   b. Study Initiation Visit
   c. Interim Study Visit
   d. Closeout Visit and study completion
      i. Data Locking
      ii. Return/Destruction of Remaining Study Agent
      iii. Final Disposition of Study Supplies
Keys to Successful Clinical Research Response

Science

Operations ↔ Strategy
Partnership Management: Critical Success Factors in Clinical Research Partnerships (1)

- The Parameters
  - Clear research need that benefits from or requires a collaborative approach
  - Common goals implemented through a strategy developed and agreed to by all partners
  - Ability to adapt to changing scientific priorities

- Those Involved
  - Investment of governments and other institutions engaged in the partnership
  - Participation of partners with authority, credibility, and capacity necessary to address the need
  - Engaged senior leadership and active operational leadership
  - Buy-in of key stakeholders
Partnership Management: Critical Success Factors in Clinical Research Partnerships (2)

- **Resources & Support**
  - Adequate resources contributed by partners (human, financial, material, etc.)
  - On-the-ground operational support

- **Structure & Processes**
  - Jointly developed organizational structure with clear roles, responsibilities, and authorities
  - Clear processes for: Partnership management, clinical research management, strategy management, governance, financial management

- **Operations**
  - Agreement on approach to management
  - Respectful, clear, timely communications
  - Proactive issue identification and problem solving
Strategy Management - Critical Success Factors

- Spend time designing effective governance structures with clearly defined and shared goals
- Include the right people involved at the right time
- Develop key metrics or an operational management system
- Value and manage the unique relationships and attitudes to change within networks
Establish a strategic plan that includes:
- Vision, mission, structure, values
- Overarching goals
- Meaningful key performance measures
- Objectives

Implement the strategic plan:
- Communicate strategy at all levels of the organization
- Establish an operational plan with objective owners, task owners, and timelines
- Cascade strategy to performance plans

Monitor, track, review progress
Strategy Management - Strategic Plan Value Added

- Formalizes expectations through network partner leadership engagement and approval
- Secures buy-in from key stakeholders
- Increases goal attainment by focusing managers & staff on activities that support vision/mission
- Fosters the development of realistic programs & project plans with clear accountability
- Aligns & maximizes resources
- Serves as communication tool for internal & external stakeholders
Planning is critical!

The future depends on what we do in the present

~ Mahatma Gandhi ~

Questions?