

# Preparing for Lassa vaccine clinical trials with targeted epidemiology studies

## Workshop objectives

**8th and 9th November 2018**

**Noguchi Memorial Institute for Medical Research, Legon, Accra, Ghana**

**Gunnstein Norheim**

# CEPIs mission

To promote the development of vaccines  
against emerging infectious diseases



enable access to these vaccines

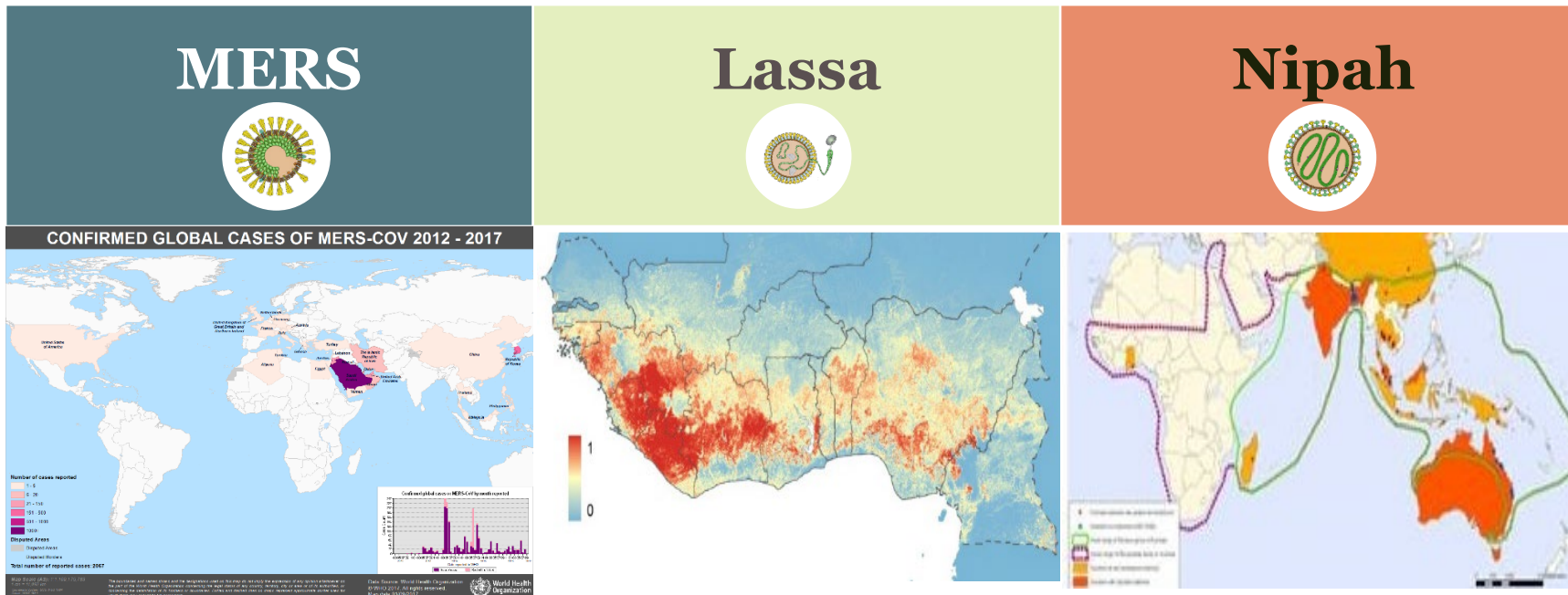
for affected populations during outbreaks

# What is CEPI?

- We're a global coalition of public, private, philanthropic, and civil society organisations
- We stimulate, finance, and coordinate vaccine development for emerging infectious diseases
- We identify priority threats and act when market forces fail to drive needed development
- We build capabilities for rapid response to unknown threats
- We move vaccine candidates through late preclinical studies to proof of concept and safety in humans before epidemics begin

# CEPI's initial priority pathogens

- WHO R&D Blueprint in 2016 for investment in medical countermeasures research
- Prioritization by CEPI Scientific Advisory Committee
  - Public health impact || Risk of an outbreak occurring || Feasibility of vaccine development



# CEPI's areas for development and facilitation

## Vaccine portfolio development

- MERS
- Nipah
- MERS-CoV

Epidemiology studies  
Facilitate Dx

Biological  
standardisation

Preclinical/immunology  
Enabling science

# Lassa Epidemiology studies - Expression of Interest

- Lassa vaccine candidates will be ready for clinical development in 2019
  - CEPI is funding targeted epidemiology studies to generate estimates of Lassa incidence across affected countries, and to facilitate the design and location of future Lassa vaccine trials
  - Builds on national surveillance, research plans, studies and the WHO Roadmap for research and development for Lassa medical countermeasures
- 10 submissions received – 7 invited for this workshop and call
  - Multiple partners and study sites per application
  - Countries: Nigeria, Guinea, Sierre Leone, Liberia and Benin

# Key questions

- What epidemiological research programs are needed in advance of potential phase I, II and III clinical trials in the next Lassa seasons?
- What data is essential, and what should be standardized between studies?
- What work is already underway, and what research gaps currently exist?
- How can Lassa fever research groups most effectively collaborate to address the unmet research needs on epidemiology data to facilitate future field evaluation of Lassa vaccines?

# Workshop objectives and outcomes

## Objectives

- Identify data needs, objectives, study designs and key harmonized elements of CEPI funded studies to facilitate vaccine development for Lassa
- Discuss options for enhanced collaboration and set up of governance of the targeted epidemiology studies to be funded by CEPI

## Expected outcomes

- A common protocol synopsis with minimum requirements for the funding call to enable comparison of the collected data between projects and sites.
- Improved insight in and options to establish collaborative consortia to address epidemiology gaps



# Workshop contents

## Day 1

### Chairs

- Vasee Moorthy, WHO
- Dicky Akanmori, WHO AFRO

### Sessions

1. Introduction
2. Lassa surveillance and research
3. Epidemiology and research needs
4. Data needs and objectives for CEPI studies

## Day 2

### Chairs

- Peter Smith, LSHTM
- Mimi Darko, FDA Ghana

### Sessions

5. Working group sessions
  - Case definition
  - Study designs & methodologies
  - Laboratory confirmation
6. Further research
7. Summary of core protocol elements
8. Partnerships and good governance
9. Next steps and close of meeting