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
CEPI’s mission

To promote the development of vaccines against emerging infectious diseases and 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

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Public health impact</th>
<th>Risk of an outbreak occurring</th>
<th>Feasibility of vaccine development</th>
</tr>
</thead>
<tbody>
<tr>
<td>MERS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lassa</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nipah</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CEPI’s areas for development and facilitation

<table>
<thead>
<tr>
<th>Vaccine portfolio development</th>
<th>Epidemiology studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>MERS</td>
<td>Facilitate Dx</td>
</tr>
<tr>
<td>Nipah</td>
<td>Biological standardisation</td>
</tr>
<tr>
<td>MERS-CoV</td>
<td>Preclinical/immunology</td>
</tr>
<tr>
<td></td>
<td>Enabling science</td>
</tr>
</tbody>
</table>
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