A workshop organised by

CEPI

in partnership with the co-hosting organisations:

Accelerating the licensure of Lassa vaccines

Generating robust evidence on vaccine efficacy and safety

25th & 26th October 2022 - Abuja, Nigeria

OBJECTIVES

- To discuss Lassa virus disease, epidemiology, and immunology
- To present current vaccine candidates under development
- To outline the design options for clinical efficacy trials for Lassa vaccines
- To develop a collaborative approach with key stakeholders to advance Lassa vaccine development and evaluation
### DAY 1: Tuesday 25 October 2022

* indicates virtual participation

<table>
<thead>
<tr>
<th>Time</th>
<th>Topic</th>
<th>Speakers</th>
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</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Welcome address</td>
<td>Jakob Cramer (CEPI)</td>
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<td></td>
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<td>Ana Maria Henao Restrepo (WHO)</td>
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<td></td>
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<td>Ifedayo Adetifa (NCDC)*</td>
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<td>Ahmed Ogwell (ACDC)*</td>
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<td>Objectives of the meeting</td>
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#### Session 1: Lassa fever disease, epidemiology, and immunology

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<tr>
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<tbody>
<tr>
<td>09:00-09:20</td>
<td>Natural history of disease</td>
<td>Sylvanus Akhalufo Okogbenin (Nigeria)</td>
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<td>Nnennaya Ajayi (Nigeria)</td>
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<tr>
<td>09:20-10:00</td>
<td>Brief overview of Lassa fever epidemiology and current surveillance systems (10 minutes each) (including Lassa fever incidence over time and demographics)</td>
<td>Jefferson Sibley (Liberia)</td>
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<td></td>
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<td>N’faly Magassouba (Guinea)</td>
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<td>Chioma Dannwafor (Nigeria)</td>
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<td>Donald Grant (Sierra Leone)</td>
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<tr>
<td>10:00-10:20</td>
<td>Preliminary data from ENABLE: A multi-country Lassa fever epidemiology study</td>
<td>Anton Camacho (Epicentre)</td>
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<tr>
<td>10:20-11:00</td>
<td>The true burden of Lassa fever disease and its implications for vaccine trial design</td>
<td>Plenary discussion, moderated by Chinwe Ochu (NCDC) and Helen Rees (WHRI)*</td>
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<tr>
<td>11:00-11:15</td>
<td>Review of Lassa fever host immune response and protective immunity</td>
<td>Sylvain Baize (Ins Pasteur)</td>
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<td>11:15-11:30</td>
<td>Coffee - break</td>
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#### Session 2: Overview Lassa fever vaccine development programs

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>11:30-11:40</td>
<td>A global TPP: What do we want to achieve with a Lassa vaccine?</td>
<td>Ana Maria Henao Restrepo (WHO)</td>
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<tr>
<td>11:40-12:20</td>
<td>What kind of Lassa fever vaccine is needed: preventive versus reactive or both?</td>
<td>Panel discussion, moderated by Tom Monath (Crozet Bio)*</td>
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<td>Donald Grant (Sierra Leone)</td>
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<td>Chinwe Ochu (NCDC)</td>
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<td></td>
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<td>Gabrielle Breugelmans (CEPI)</td>
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<td>Sylvanus Akhalufo Okogbenin (Nigeria)</td>
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<td>David Wohl (UNC)</td>
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<td>Delia Enria (INEVH)*</td>
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<td>12:20-12:50</td>
<td>Landscape review of LF vaccines (7 minutes each) (Developers to present vaccine candidate, development status and plans)</td>
<td>Sarah Gilbert (Oxford)</td>
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<td>Swati Gupta (IAVI)</td>
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<td>Bon Orizu (Inovio)</td>
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<td>Gideon Akintunde (Emergent)</td>
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**Session 3: Designing Phase 3 efficacy trials for Lassa fever vaccines**

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<tbody>
<tr>
<td>14:30-14:40</td>
<td>Efficacy trials of Lassa vaccines: endpoints, trial design, site selection (Objectives, endpoints and success criteria, trial populations)</td>
<td>Ana Maria Henao Restrepo (WHO)</td>
</tr>
<tr>
<td>14:40-14:50</td>
<td>Considerations on case definitions and potential secondary / exploratory objectives &amp; endpoints</td>
<td>Paul Oloo (CEPI)</td>
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</table>
| 14:50-15:15| Statistical considerations re trial design and sample size              | - Ira Longini (U Florida)*  
- Bob Small (CEPI)*                                                                                                                                                                           |
| 15:15-15:25| Considerations for a safety assessment                                  | Steve Black (SPEAC)                                                                                                                                                                               |
| 15:25-16:10| In light of recent epidemiologic data and the above deliberations, what adjustments to the protocol should be considered?  
- Primary, secondary, exploratory objectives / endpoints  
- Case definitions  
- Trial populations  
- Other | Panel discussion, moderated by Elizabeth Higgs (NIAID)*  
- Bob Small (CEPI)*  
- Ira Longini (U Florida)*  
- Steve Black (SPEAC)  
- Ana Maria Henao Restrepo (WHO)  
- Paul Oloo (CEPI)  
- David Wohl (UNC)  
- Simeon Cadmus (Nigeria)                                                                                                                                 |
| 16:10-16:30| Experiences in multi-country trials and platform trial approaches      | - Solidarity 3 COVID-19  
- Ebola vaccine trials  
- Samba Sow (Mali)*  
- Stephen Kennedy (Liberia)                                                                                                                                                                     |
| 16:30-16:50| A multi-national consortium to coordinate and facilitate vaccine(s) evaluation (10 min each)  
- Marburg consortium  
- Meningitis vaccine project | - Cesar Muñoz Fontela, (BNITM)*  
- Andre Bita (WHO)*                                                                                                                                                                              |
| 16:50-17:30| Coffee – break                                                         |                                                                                                                                                                                                     |

**Session 4: Working group sessions**

| 17:30 – 18:30 | GROUP 1. Proposed trial design and implementation  
GROUP 2. Regulatory and policy considerations  
GROUP 3. Collaborative approach to evaluate Lassa fever vaccines | Ana Maria Henao Restrepo (WHO)  
Phil Krause  
Caroline Forkin (CEPI)                                                                                                                                 |
<p>| 18:30         | ADJOURN DAY 1                                                           |</p>
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<tr>
<td>08:30-09:30</td>
<td>Outcomes of WG deliberations (10 minutes presentation / discussion each)</td>
<td>Group 1. Proposed trial design and implementation&lt;br&gt;Group 2. Regulatory and policy considerations&lt;br&gt;Group 3. Collaborative approach and to evaluate Lassa fever vaccines&lt;br&gt;&lt;i&gt;Open discussion on the WG deliberations&lt;/i&gt;</td>
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<td>09:30-10:10</td>
<td>How to prepare for a trial considering disease incidence is a random event? (Use of same case definitions, Lassa fever case definition, fit-for-purpose instruments e.g. laboratory assays)</td>
<td>Panel discussion, moderated by Jean Marie Habarugira (EDCTP)<em>&lt;br&gt;Clinical researchers’ perspectives • Jefferson Sibley (Liberia)&lt;br&gt;• N’faly Magassouba (Guinea)&lt;br&gt;• Olayinka Adegbola (Nigeria)&lt;br&gt;• Ayola Akim Adegnika (Gabon)&lt;br&gt;• Robert Samuel (Sierra Leone)&lt;br&gt;• Enogo Koivogui (Guinea)</em></td>
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<td>10:10-10:30</td>
<td>Community engagement and good participatory practices: lessons learned and existing tools</td>
<td>Nina Gobat &amp; Julienne Anoko (WHO)*</td>
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<tr>
<td>10:30-10:40</td>
<td>A transparent framework for selecting vaccines to be evaluated in Phase 2b/Phase 3 trials – experience from COVID vaccines</td>
<td>Elizabeth Miller (LSHTM)*</td>
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<td>10:40-10:50</td>
<td>The role of a single DSMB and the outline of the governance framework for the trials</td>
<td>Steve Black (SPEAC)</td>
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<td>10:50-11:20</td>
<td>Coffee - break</td>
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<td>11:20-11:40</td>
<td>Ensuring equitable access: • The Partnerships for African Vaccine Manufacturing (PAVM) initiative • CEPI provisions</td>
<td>• Nicaise Ndemb (A-CDC)&lt;br&gt;• Marion Motari (CEPI)*</td>
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<tr>
<td>11:40-12:40</td>
<td>Lassa fever Phase 3 vaccine efficacy trial: collaborative approach</td>
<td>Plenary, moderated by Nicole Lurie (CEPI) &amp; Phil Krause</td>
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<td>12:40-13:50</td>
<td>Lunch – break</td>
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<td>Time</td>
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<td>Speakers</td>
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<td>13:50-14:00</td>
<td>Effectiveness of Ribavirin</td>
<td>Jonathan Sterne &amp; Hung-Yuan Cheng (U Bristol)*</td>
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<td>14:00-14:10</td>
<td>Towards use of standardized assays: the role of a central lab</td>
<td>Valentina Bernasconi (CEPI)*</td>
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<td>14:10-14:20</td>
<td>Diagnostics: performance evaluation and access</td>
<td>Devy Emperador (FIND)*</td>
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<td>14:20-14:30</td>
<td>Other Lassa fever research priorities relevant for vaccine evaluation</td>
<td>Robert Garry (Tulane)*</td>
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<td>14:30-15:00</td>
<td>Are there any other research priorities or enabling actions that need to be considered?</td>
<td>Panel discussion, moderated by Bola Jones (CEPI)</td>
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<td>• Robert Garry (Tulane)*</td>
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<td>• Stephan Guenther (BNITM)</td>
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<td>• David Wohl (UNC)</td>
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<td>15:00-15:30</td>
<td>Coffee – break</td>
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<tr>
<td>15:30-16:00</td>
<td>Review and alignment of workshop outcomes</td>
<td>All</td>
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| 16:00-16:30  | Summary of next steps (including establishing a forum for regular interactions) | Phil Krause  
 |              |                                                                      | Ana Maria Henao Restrepo (WHO)                                         |
|              |                                                                      | Jakob Cramer (CEPI)                                                     |
| 16:30        | END OF MEETING                                                       |                                                                          |