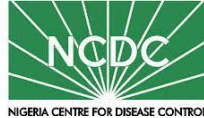


A workshop organised by



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

Time	Topic	Speakers
08:30-09:00	Welcome address	Jakob Cramer (CEPI) Ana Maria Henao Restrepo (WHO) Ifedayo Adetifa (NCDC)* Ahmed Ogwell (ACDC)*
	Objectives of the meeting	Chairperson: Nicole Lurie (CEPI)
Session 1: Lassa fever disease, epidemiology, and immunology		
09:00-09:20	Natural history of disease - Clinical Features of Lassa fever in Nigeria - Clinical management of Lassa fever Disease	- Sylvanus Akhalufo Okogbenin (Nigeria) - Nnennaya Ajayi (Nigeria)
09:20-10:00	Brief overview of Lassa fever epidemiology and current surveillance systems (10 minutes each) (including Lassa fever incidence over time and demographics)	- Jefferson Sibley (Liberia) - N'faly Magassouba (Guinea) - Chioma Dannwafor (Nigeria) - Donald Grant (Sierra Leone)
10:00-10:20	Preliminary data from ENABLE: A multi-country Lassa fever epidemiology study	Anton Camacho (Epicentre)
10:20-11:00	The true burden of Lassa fever disease and its implications for vaccine trial design	Plenary discussion, moderated by Chinwe Ochu (NCDC) and Helen Rees (WHRI)*
11:00-11:15	Review of Lassa fever host immune response and protective immunity	Sylvain Baize (Ins Pasteur)
11:15-11:30	Coffee - break	
Session 2: Overview Lassa fever vaccine development programs		
11:30-11:40	A global TPP: What do we want to achieve with a Lassa vaccine?	Ana Maria Henao Restrepo (WHO)
11:40-12:20	What kind of Lassa fever vaccine is needed: preventive versus reactive or both?	Panel discussion, moderated by Tom Monath (Crozet Bio)* - Donald Grant (Sierra Leone) - Chinwe Ochu (NCDC) - Gabrielle Breugelmans (CEPI) - Sylvanus Akhalufo Okogbenin (Nigeria) - David Wohl (UNC) - Delia Enria (INEVH)*
12:20-12:50	Landscape review of LF vaccines (7 minutes each) (Developers to present vaccine candidate, development status and plans)	- Sarah Gilbert (Oxford) - Swati Gupta (IAVI) - Bon Orizu (Inovio) - Gideon Akintunde (Emergent)

Time	Topic	Speakers
12:50-13:20	Potential regulatory pathways towards vaccine licensure	Panel discussion, moderated by Phil Krause • Beno Yakubu (Nigeria NRA) • Fawzi Thomas (SL NRA) • Rogerio Gaspar (WHO)* • Danielle Craig (CEPI)
13:20-13:30	Q&A	Plenary led by Nicole Lurie (CEPI)
13:30-14:30	Lunch - break	
Session 3: Designing Phase 3 efficacy trials for Lassa fever vaccines		
14:30-14:40	Efficacy trials of Lassa vaccines: endpoints, trial design, site selection (Objectives, endpoints and success criteria, trial populations)	Ana Maria Henao Restrepo (WHO)
14:40-14:50	Considerations on case definitions and potential secondary / exploratory objectives & endpoints	Paul Oloo (CEPI)
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 Bitá (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)
18:30	ADJOURN DAY 1	

DAY 2: Wednesday 26 October 2022

Time	Topic	Speakers
		Chairperson: TBC
08:30-09:30	Outcomes of WG deliberations (10 minutes presentation / discussion each) GROUP 1. Proposed trial design and implementation GROUP 2. Regulatory and policy considerations GROUP 3. Collaborative approach and to evaluate Lassa fever vaccines <i>Open discussion on the WG deliberations</i>	Moderated by Denis Malvy (Inserm)* Ana Maria Henao Restrepo (WHO) Phil Krause Caroline Forkin (CEPI)
Session 5: Ways forward and opportunities for collaboration		
09:30-10:10	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)	Panel discussion, moderated by Jean Marie Habarugira (EDCTP)* Clinical researchers' perspectives • Jefferson Sibley (Liberia) • N'faly Magassouba (Guinea) • Olayinka Adebola (Nigeria) • Ayola Akim Adeginka (Gabon) • Robert Samuel (Sierra Leone) • Enogo Koivogui (Guinea)*
10:10-10:30	Community engagement and good participatory practices: lessons learned and existing tools	Nina Gobat & Julienne Anoko (WHO)*
10:30-10:40	A transparent framework for selecting vaccines to be evaluated in Phase 2b/Phase 3 trials – experience from COVID vaccines	Elizabeth Miller (LSHTM)*
10:40-10:50	The role of a single DSMB and the outline of the governance framework for the trials	Steve Black (SPEAC)
10:50-11:20	Coffee - break	
11:20-11:40	Ensuring equitable access: • The Partnerships for African Vaccine Manufacturing (PAVM) initiative • CEPI provisions	• Nicaise Ndembi (A-CDC) • Marion Motari (CEPI)*
11:40-12:40	Lassa fever Phase 3 vaccine efficacy trial: collaborative approach	Plenary, moderated by Nicole Lurie (CEPI) & Phil Krause
12:40-13:50	Lunch – break	

Time	Topic	Speakers
Session 6: Other enabling activities		
13:50-14:00	Effectiveness of Ribavirin	Jonathan Sterne & Hung-Yuan Cheng (U Bristol)*
14:00-14:10	Towards use of standardized assays: the role of a central lab	Valentina Bernasconi (CEPI)*
14:10-14:20	Diagnostics: performance evaluation and access	Devy Emperador (FIND)*
14:20-14:30	Other Lassa fever research priorities relevant for vaccine evaluation	Robert Garry (Tulane)*
14:30-15:00	Are there any other research priorities or enabling actions that need to be considered?	Panel discussion, moderated by Bola Jones (CEPI) • Robert Garry (Tulane)* • Stephan Guenther (BNITM) • David Wohl (UNC)
15:00-15:30	Coffee – break	
Session 7: Next steps		
15:30-16:00	Review and alignment of workshop outcomes	All
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	