

Session objectives

Agree on diagnostic approach, including preferred method and minimal standards for:

- molecular test to confirm LASV
- serological test
- LASV sequencing
- Agree on commonly used protocol on laboratory methods
- Gain knowledge on main challenges in lab diagnostic of different sites and any other useful information to be collected

Molecular tests

A. What are the current molecular tests used in different research sites ?

- **2 Conventional PCR and 2 Rt-PCR**

B. Can we use the same RT-PCR method and diagnostic algorithm for all study sites to ensure comparability?

- **Yes, Conventional PCR and Rt-PCR using blood (plasma)**
- If so, which RT-PCR assay would be most fit for purpose for the use case of case confirmation for a vaccine efficacy trial that should be utilized by all sites?
 - **4 countries using the same assays (Altona, Nikkisins)**
 - **We need to validate these RT-PCR using a defined panel of Lassa strains**
- What validation needs to be done?
 - **FIND and WHO are validating Nikkisins assays**
 - **Existing validation for the Altona 1.0**
 - **All other molecular assays currently in use**

Serological test

a. Do we need the same serological test for all sites to enable comparison? **Yes,**

i. If yes; which serological test should be used?

- 5 serological tests: Ag capture IgM and IgG, Recombinant Lassa Virus ELISA, Mag PIX, Immunofluorescence based on NP and GP

ii. If no; how do we enable comparison between sites?

- Well characterized sample panels, standardized, equipment, reagents and antigens

Genome sequence

a. To what extent is LASV genome sequencing implemented in each of the study countries to obtain information on clade/strain?

- **Done: Nigeria, Sierra Leone**
- **Not done: Guinea, Benin (support by BNI)**
- **Done outside: Liberia**

b. Is there any LASV genome sequencing data gap? **Yes, not enough data**

- **Lack of in country capacity**

If yes, what study design implications are there to ensure such data are gathered to inform vaccine design?

i. Each country needs to plan for generating spatiotemporal data on sequencing

ii. Set minimum criteria for number of samples and frequency

ii. If yes, how should genome sequencing and data be performed on a more regular basis as part of the proposed? **Yes**

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Other information

- What are the main barriers to implement RT-PCR in the different research sites (e.g. sample transport time, human resources and expertise, reagents, electricity etc)?
 - **Funding for consumables and reagents**
 - **Issues of Supply chain, biosafety, cold chain, specimen repository**
- As part of implementing the WHO R&D Blueprint recommendation on data and sample sharing, how can a sample sharing mechanism and agreement among the consortium members?
 - **Possible: MOU, MTA**
- What data (beyond data on sample should be collected across all countries to show the entire process from collection to result (e.g. transportation time from collection to the lab; lab turnaround time from receipt of sample to result etc)
 - **Basic lab SOPS need to be established**
 - **Specific technical capacity should be built and resources needed to maintain**
 - **Capacity to train biomedical engineers**