

Collaborative approach to evaluating Lassa fever vaccines

Topics for consideration

Accelerating the Licensure of Lassa Vaccines

October 25th & 26th 2022

Abuja, Nigeria

For Consideration

Collaboration is the.....***Who, What, When, Where, Why and How***

- Trial Design and Regulatory Considerations are black & white by comparison
- Collaboration is a complex and very grey area, easy to discuss and consider but extremely challenging in practice
- We all pay lip service but takes commitment, compromise and an ability/willingness to concede control at times.....

Are we there yet?

For Consideration

Collaboration is the.....**Who, What, When, Where, Why and How**

Who?

- Are we clear who the stakeholders are and how/when they will be engaged?
- What Governance structure is appropriate/feasible?
and.....
- Who decides on the final protocol design?
- Who defines the roles and responsibilities and at what levels?

For Consideration

Collaboration is the.....*Who, **What**, When, Where, Why and How*

What?

- Clarity on the regulatory pathway
- Agreement on the trial design
- Multiple countries prepared to implement a phase 3 clinical trial
- Vaccine prioritisation
- Funding secured

For Consideration

Collaboration is the.....*Who, What, When, Where, Why and **How***
How?

- Build the infrastructure (physical and other....)
- Capacity-build for sustainability (don't reinvent the wheel)
 - GCP-compliant clinical trials but other considerations
- Leverage regional expertise and capacity – central lab?
- Community mobilisation and communication

