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