WHO Workshop – Efficacy trials of ZIKV vaccines

endpoints, trial design, site selection
WHO Blueprint Plan of Action

A. Improving coordination & fostering an enabling environment
B. Accelerating Research & Development processes
C. Developing new norms & standards tailored to the epidemic context

Implementing adequate study designs
Context

- Feb - Nov 2016: PHEIC of Zika virus and the clusters of microcephaly cases and other neurological disorders
- No licensed ZIKV vaccines
- More than 45 vaccine candidates in development
WHO efforts with collaborative partners to accelerate Zika Vx R&D

- Zika R&D summit
- WHO Regulatory Consultation
- NIH/WHO Scientific Consultation
- WHO Workshop Efficacy trials
- CT workplan starts
- Vx TPP Emergency Use
- Global Coordination Mechanism meeting Zika Vx R&D
- WHO Blueprint Plan of Action (Priority Pathogens)
- Vx TPP Update

Epi curve in Brazil, *source MoH*
Workshop - Zika efficacy trials

Aim

For ZIKV vaccines, provide informed methodological recommendations on:

1. Clinical and immunological endpoints
2. Clinical trial design
3. Site selection
Workshop - Zika efficacy trials

Principles of recommendation

- Supportive of Public Health objectives

- Regardless of product

- Identifying methodological options and judge options
  - based on review of available scientific evidence
  - based on lessons learned from flavivirus