

## **Topics for VRBPAC Discussion**

1. **Discuss the following aspects of clinical studies to assess effectiveness of CHIK vaccines:**
  - Feasibility of randomized, controlled clinical disease endpoint efficacy trials
  - Role of sero-epidemiologic data in identifying an immune marker reasonably likely to predict vaccine effectiveness
  
2. **Discuss the utility of the non-human primate (NHP) challenge model to assess effectiveness of CHIK vaccines, including:**
  - Effectiveness endpoints, such as viremia, arthritis-related endpoints or other essential endpoints
  - Role of passively transferred sera or purified IgG from vaccinated humans in identifying an immune marker reasonably likely to predict vaccine effectiveness
  - Whether additional information is needed to support the utility of the NHP challenge model