



OUR EXPERIENCE WITH CHIKUNGUNYA VIRUS

The FHI Clinical project team has partnered with the US government and contracted companies to develop a vaccine for Chikungunya virus (CHIKV) in CHIKV-endemic areas of Caribbean countries.



IMPACT OF CHIKV

CHIKV outbreaks have occurred in countries in Africa, Asia, Europe, and the Indian and Pacific Oceans. It was found for the first time in the Americas on islands in the Caribbean in 2013 and has spread throughout most of the Americas. It has since been identified in over 60 countries in Asia, Africa, Europe and the Americas. No commercially available vaccine to prevent or medicine to treat CHIKV infection is currently available.

CHALLENGES WITH CHIKV RESEARCH

- **Locations with limited research capacity, including regulatory processes for study protocol and product approvals**
- **Remote and inaccessible geographical outbreak areas**
- **Poor surveillance systems**
- **Migrant populations**
- **Difficult to clinically distinguish CHIKV from dengue and Zika**

World Health Organization, <https://www.who.int/emergencies/diseases/chikungunya/en/>

COMPLETED CHIKV STUDIES WITH FHI CLINICAL INVOLVEMENT

DOMINICAN
REPUBLIC
GUADELOUPE
HAITI
MARTINIQUE
PUERTO RICO



Read case study at
FHIClinical.com

GOVERNMENT SPONSOR

Study Duration: 2015-2018

Phase: II

Study Title: Phase 2 randomized, placebo-controlled trial to evaluate the safety and immunogenicity of a Chikungunya virus-like particle vaccine, VRC-CHKVLp059-00-VP, in healthy adults.

ClinicalTrials.gov Identifier:
NCT02562482

FHI Clinical's Roles:

- Site and investigator identification
- Site assessment
- Regulatory submissions and reports
- Site initiation
- Site management
- Laboratory support
- Cold chain assessment and management

Outcomes:

- The study team achieved a 91% retention rate despite study disruptions due to natural disasters and political unrest.
- Enrollment was completed in October 2016, one year after the first site was activated.



Global expertise, responsive approaches and proven solutions to manage complex clinical research in resource-limited settings around the world. To learn more, visit fhiclinical.com or email info@fhiclinical.com.