Case Study | 7th September 2022

Deployment of a hybrid decentralized clinical trial for the validation of a serological diagnostic test for the screening and follow-up of patients infected with the dengue virus

Patient Recruitment | Hybrid Decentralized Clinical Trial | Observational Multicentric Study | IVD Clinical Performance | Data Management

The Case

Infection with any of the 4 dengue virus serotypes results in a diverse range of symptoms. Given that dengue virus infection elicits such a broad range of clinical symptoms, early and accurate laboratory diagnosis is essential for appropriate patient management.

In order to meet this challenge, our client, a leading pharmaceutical laboratory, has developed a serological test for the detection and serological conversion of 3 dengue virus serotypes (DENV1, DENV3 and DENV4) throughout the progression of the disease.

The Challenges

Regulatory expertise for the detailed writing and justification of the decentralized elements of the protocol and its submission to the ethics committee.

Identification within our network of routine laboratories of eligible patients meeting the inclusion criteria.

Development of a robust strategy to ensure collection of biological samples and data from recruited patients at 4-time points (D0 at the inclusion site, then D5, D14, D90 at home).

Coordination and transportation of collected samples, ensuring quality control and delivery to our customers in compliance with storage conditions.

How We Responded

Establishment of an expert working group dedicated to the project (pathologist, clinical research associates, a project manager, and a data manager).

Establishment of a statistical study on our entire network of routine laboratories in order to identify the region with high prevalence of the virus as well as the right period to start the inclusions.

Setting up of 2 sites on the island of La Réunion enabling the screening of 200+ patients and enrolment of 26 patients.

Implementation of a network of home nurses to collect biological samples and clinical data over a 3-month period.

Top Takeaways

All samples were successfully collected and transported to our client by the estimated date.

The close collaboration and coordination between the investigation sites, our CRAs, and the home nurses allowed the project to be carried out smoothly and ensured proper observance.

This pilot study has allowed the integration of hybrid DCTs within our network, especially in the case of dengue disease, where symptoms get severe in the first two weeks, preventing the patient from attending follow-up visits.

Timeline

Jan '21	Jun '21	Jun '21	Jun '21 – Jul '22 (13 months)	Jul '2022
Submissions to ethical committee	Start up	First inclusion	Inclusion period	Final report

Cerba Research