CASE STUDY

George Clinical
Science. Service. Solutions.

New Formulation ROTAVAC 5C Has the Lowest Cold Chain Footprint Amongst Oral Rotavirus Vaccine in the World.

Seamless coordination of complex pediatric Phase III clinical trial for ROTAVAC 5C® in India brings world closer to improving the global supply of affordable rotavirus vaccines.

SITUATION

George Clinical was selected by sponsor Bharat Biotech to conduct a seamless, sequential Phase III, randomized, multi-center, single-blind study to evaluate immunogenicity, safety and reactogenicity of liquid ROTAVAC 5C formulation of the live attenuated rotavirus vaccine as a 3-dose series when compared with ROTAVAC in infants. Highly contagious rotaviruses are the leading cause of severe diarrheal illnesses among infants and young children in both developed and resource-limited countries. Each year, rotavirus-induced diarrheal disease kills roughly 213,000 children younger than 5 years old and hospitalizes an estimated two million children worldwide, largely in developing countries. The youngest children—those between 6 months and 2 years of age—are most vulnerable.

ROTAVAC (based on the 116E strain) became the first indigenously developed vaccine from India to be pre-qualified by World Health Organization (WHO), thus allowing the vaccine to be sold internationally to several countries in Asia and Africa. The previous formulation of the vaccine had to be kept frozen at −20°C, causing practical challenges in the field.

This clinical trial implemented by the multi-disciplinary team at George Clinical compared the safety and immunogenicity of a new generation of ROTAVAC to the original formulation and also evaluated the non-interference of the new formulation with EPI vaccines.

The new generation has been optimally designed for ease of administration, reduced training requirements and a lower cold chain footprint. The new formulation can be refrigerated, resulting in significant savings in cold chain storage and distribution costs. The ROTAVAC 5C formulation now has the lowest cold chain footprint of amongst rotavirus vaccine in the world.

Key Results

SWIFT START
All Sites Initiated
Within 2 Weeks

EARLY RECRUITMENT
700 Exploratory Subjects
2.5 Months

1,300 Confirmatory Subjects
7 Months

ON-TIME DATA
All Data Timelines Met

AUDITS & INSPECTIONS
0 Critical Findings

George Clinical was selected for this contract based on a competitive quote, our reputation as a high quality provider and our bespoke solutions that focus on the customer's specific needs. In addition, as a global provider of clinical research services, George Clinical already had ground personnel in Hyderabad and Bangalore to assist in services rendered including project management, clinical and medical monitoring, pharmacovigilance, data management, statistics and medical writing.

"India has been a core country for our clinical trial services for 10 years, as well as being a leader in The George Institute's public health activities for more than a decade. Supporting one of the leading biotech companies in India on this study, which will have an immediate impact on India's children, is very satisfying," stated Dr. Marisa Petersen, former CEO, George Clinical.

CHALLENGES

Sponsors of the clinical trial required fast-paced recruitment and data entry as well as first-rate data. The sites that George Clinical worked with did not have extensive experience in clinical trials, so the team needed to be certain that those sites had all the necessary support and input needed throughout the process. In addition, the team also coordinated with a site management organization that was involved in the trial. The subjects were healthy infants, which added an extra layer of difficulty in obtaining parental consent for a clinical trial. And as this population of trial participants was seen primarily in the outpatient setting, this also introduced challenges in regards to source document collection. With an investigational product that required strict temperature control at all times, storage and logistics needed to be precisely monitored.

SOLUTIONS

The multidisciplinary team at George Clinical quickly streamlined communication channels involving sponsors, George Clinical, trial sites and the site management organization. A robust infrastructure was established with back-up arrangements and check controls for aspects such as lab sample storage and logistics. Site staff and investigators were given intense, good clinical practice training with regular follow-up and monitoring of these practices. Close communication with the site and IP logistics vendor was maintained at all times.

RESULTS

The seamless coordination of activities between the George Clinical team and the sponsor resulted in the project moving forward rapidly and smoothly.

- Swift start: All sites initiated **within two weeks** from the regulatory/ethics approval
- Recruitment targets met: All targets met **ahead of time** with 700 exploratory phase subjects in 2.5 months and 1,300 confirmatory phase subjects in 7 months
- Data timelines met: Data entry, data query resolution were met in required timelines and database locked in time
- No critical findings from site audits and regulatory inspections

The product is successfully made ready for Licensure.

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