

First WHO Emergency Use License: Crucial Polio Vaccine Approval



Introduction

To address risks associated with an older type 2 oral polio vaccine, the Gates Foundation embarked on a transformative project. The traditional type 2 oral polio vaccine, while instrumental in reducing polio cases worldwide, had a significant drawback:

- In rare instances, it could mutate and cause vaccine-derived poliovirus outbreaks.
- This risk was particularly concerning in developing countries with limited healthcare infrastructure, where an outbreak could rapidly escalate.
- To mitigate this danger, the Gates Foundation aimed to develop a new, safer version of the type 2 oral polio vaccine.
- To achieve this, they needed a reliable partner with the expertise and infrastructure to conduct extensive clinical trials.
- VaxTrials emerged as a key player in this critical effort, conducting trials in Latin America, a region ideally suited for this effort due to high vaccination rates and a lower risk of infectious outbreaks.

Challenges Faced During the Trials

Conducting clinical trials for a new polio vaccine in regions where the disease had not been a public health issue for over three decades presented several challenges. First, encouraging parents to enroll their children in the trial required extensive education about polio and its global impact. Convincing them of the trial's importance, despite the absence of polio in their communities, was a significant hurdle. Moreover, there were logistical complexities, as sites required continuous supplies of the new vaccine during the enrolment.

Additionally, to assess whether the vaccine had mutated into vaccine derived poliovirus, the trial required more than 70,000 stool samples be shipped to the CDC lab in Atlanta for analysis. This demanded impeccable logistical coordination to ensure sample integrity and timely delivery. Furthermore, securing government approvals across multiple Latin American countries was crucial for smooth trial operations and compliance with local regulations. Lastly, the trials had to be completed before the older type 2 oral polio vaccine was phased out in many Latin America countries, adding immense pressure to the timeline.



Logistical complexities, **AS SITES REQUIRED CONTINUOUS SUPPLIES**



The trial required enrolling patients in regions where the **DISEASE WAS NOT A PUBLIC HEALTH ISSUE**



Sample integrity and **TIMELY DELIVERY**



Trials had to be completed **BEFORE THE OLDER TYPE 2 ORAL POLIO VACCINE WAS PHASED OUT**

Solutions Implemented by VaxTrials



EDUCATIONAL CAMPAIGNS to inform parents about the trial's significance



TRANSPORTATION OF OVER 70,000 STOOL SAMPLES to the CDC



The team secured necessary **GOVERNMENT APPROVALS SWIFTLY**



VaxTrials executed the study's with **CONTINUITY AND VALIDITY.**

VaxTrials crafted targeted educational campaigns to inform parents about the trial's significance. These campaigns included comprehensive explanations of the risks and benefits, highlighting the altruistic impact on global health. VaxTrials also designed informed consent forms that were easy to understand emphasizing the global importance of the trial. This fostered trust and willingness among parents to enroll their children, ensuring high participation rates despite potential risks. Leveraging their logistics expertise, VaxTrials also meticulously planned and executed the transportation of over 70,000 stool samples to the CDC. They ensured no lost shipments or invalidated samples through robust oversight by a highly skilled internal team, maintaining the highest standards of sample integrity

The expertise of the VaxTrials team was pivotal to the trial's success. The team secured necessary government approvals swiftly, ensuring compliance and smooth trial operations. This collaboration with regulatory bodies across Latin America facilitated smoother operations and contributed significantly to the trial's success. Additionally, the team's flexibility enabled them to adapt to the changing regulatory environment, creating a retrospective cohort prior to withdrawal of the older type 2 oral polio vaccine. VaxTrials executed the retrospective cohort study with remarkable speed, ensuring the overall study's continuity and validity.

The trials conducted by VaxTrials yielded significant results, contributing to the global fight against polio. Throughout the trial:

6,400
participants were
enrolled,

Over 70,000 stool
samples were collected
and analyzed

And more than
90,000 visits were
conducted over two years.

Results and Outcomes

Three vaccines, including nOPV2, were licensed, with nOPV2 becoming the first vaccine listed under the WHO's Emergency Use Listing procedure in November 2020. Since March 2021, nearly 1 billion doses of nOPV2 have been administered across 35 countries, protecting millions of children against polio. In December 2023, the novel oral polio vaccine type 2 (nOPV2) received WHO prequalification, enabling broader access and a more sustainable response to type 2 vaccine derived poliovirus outbreaks.

VaxTrials demonstrated exceptional capability in conducting large-scale, complex clinical trials under tight deadlines. Their comprehensive approach, from effective participant recruitment to robust logistical management and securing regulatory approvals, was instrumental in the successful introduction of new polio vaccines. Through their efforts, VaxTrials has significantly contributed to global public health, helping to protect millions of children from polio and reinforcing their position as a leader in vaccine development.



“The successful approval of nOPV2 vaccine highlights the pivotal role played by VaxTrials during the trial phase, in collaboration with other key stakeholders. Their innovative approach to the clinical trial operations was instrumental in receiving an Emergency Use Listing authorization from the World Health Organization, a first for a vaccine candidate. With the EUL listing the Global Polio Eradication Initiative (GPEI) has been able to deliver more than 1.2 billion doses of nOPV2 worldwide, achieving a significant health impact.”

Dr. Ananda Sankar Bandyopadhyay - Deputy Director, Polio Team | Bill & Melinda Gates Foundation