

ROTAVAC® (nHRV) – Product Development and Programmatic Implementation

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ROTAVAC® (nHRV) has been licensed in India and has received WHO Prequalification for supply to UN Agencies. ROTAVAC® was introduced into the Universal Immunization Program in India during 2016, has now been expanded across the country. ROTAVAC® was introduced in Palestine in 2018 and is scheduled for introduction in several countries in Africa, Asia, and Latin America.

ROTAVAC® was evaluated extensively in several controlled clinical trials prior to licensure. It was evaluated in a Phase III trial with 6800 subjects resulting in an efficacy of 56.4% and 48.9% in the first year and second year of life respectively, showing continued protection during the first two years of life.

The effect of buffers was evaluated in ROTAVAC®, which showed its ability to seroconvert at the same levels with and without buffers, it is the only vaccine to be administered without a buffer. Currently, a Phase IV study is underway in ~ 200,000 subjects to study the safety of ROTAVAC®. With trials ongoing in Vietnam, Zambia, and Palestine, ROTAVAC® has proven its suitability in a wide range of countries.

With product and administration profiles similar to OPV, ROTAVAC® is ideally suited for introduction into immunization programs. ROTAVAC® has a dose volume of 0.5 ml/dose, the lowest in the world. This volume assures the delivery of 100% of the intended dose, avoiding spit ups in infants. A low cold chain footprint (~ 3.2 cm³/dose) and multi dose presentations in 5 and 10 doses/vial, reduces the costs of international shipping, in country transportation, storage and biomedical waste disposal costs.

Storage at 2-8°C is a preferred characteristic. We developed various formulations with stabilizers to make this vaccine stable. A next generation, ROTAVAC® 5D, with a shelf life of 24 months and VVVM7, is now licensed in India with WHO Prequalification in process.

ROTAVAC® is currently undergoing registration in several countries and has fifteen publications and five patents (granted globally in USA, EU, India, China, Japan). With more than 70 million doses delivered to date, ROTAVAC® is well accepted globally.