

PRODUCT DEVELOPMENT AND PROGRAMATIC IMPLEMENTATION OF TYPBAR TCV® AND ROTAVAC® VACCINES

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TYP TCV® from Bharat Biotech, is the First Typhoid Conjugate Vaccine Prequalified by WHO. It is the first typhoid vaccine, clinically proven to be administered to children from 6 months of age to adults and confers long term protection against salmonella typhi.

International Health Metrics and Evaluation (IHME) estimates that in 2016, there were approximately 12 million cases of typhoid fever resulting in around 130,000 deaths. In most developing countries the cost of a course of treatment for typhoid fever ranges from \$50 to \$5000 for outpatient and inpatient treatments.

TYPBAR TCV® is a result of dedicated product development at Bharat Biotech since 2001, with the strains provided by Dr. John Robbins, where all aspects of the product profile were studied and evaluated in human clinical trials. With 5 years of follow up data for seroconversion, TYPBAR TCV® at 25µg / dose has proven long term protection for children and adults alike and can be administered to children from 6 months of age and WHO-SAGE recommended the use of typhoid conjugate vaccines for use in infants between 6 and 23 months of age and catch up vaccinations for children between 2 and 15 years of age. This recommendation paves the way for countries to introduce the vaccine into their immunization programs. Oxford University conducted a human challenge study with TYPBARTCV®, where the subjects were challenged with live S. Typhi proving a protective efficacy of 87% against typhoid fever.

Rotavirus is the leading cause of severe diarrhoea and death among children less than five years of age around the world. According to a recent study, 37 percent of the 578,000 childhood diarrheal deaths in 2013 were due to rotavirus.

Vaccinations are an important part of global public health efforts to meet the Sustainable Developmental Goals of UNDP. ROTAVAC® was developed as a result of a multi country - multi partner collaborative model of Team science for over 2 decades and has covered all aspects of product development, licensure, and WHO prequalification, and represents a true reflection of “Clone to Clinic to Global Access”, resulting in a lifesaving product for global populations. The product profile of ROTAVAC® has been optimally designed for the developing world by the developing world to aid ease of administration, reduced training requirements, and with the lowest cold chain footprint for an oral rotavirus vaccine in the world.

The project to develop ROTAVAC® has resulted in more than 15 international publications in peer reviewed journals, including the pivotal phase III publication in Lancet in 2014 proving its comparable efficacy in the developing world. ROTAVAC® has 5 global patents, granted in countries such as India, USA, UK, South Africa, China, Nigeria, among several others. Product registrations for ROTAVAC® are in process in more than 30 countries globally.