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The journey of Rotavac

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With his tireless stint in fostering this partnership and ensuring the highest standards for the vaccine all these years, Dr M K Bhan, former secretary, department of biotechnology (DBT) was highly elated when the official announcement regarding trial results of Rotavac vaccine was made by the DBT and Bharat Biotech, on May 14, 2013 at New Delhi.

His belief, what Dr Bhan points out, in the system of the country, kept the efforts multiplying and project expanding. "We must have full faith in our ability to do science and ignore unnecessary criticism. I believe in system and not advocacy," he said while humbly appreciating the international and national partners for their efforts. "Having dealt with poor children my all my life, I have seen how severe is the hospital management and therefore I am happy to see that we would emerge as suppliers of these affordable vaccines for underprivileged."

26 years of striving: A glance at the progress

â—„ **1985-86:** Dr M K Bhan discovers strain, 116E during his routine testing at All India Institute of Medical Sciences (AIIMS), New Delhi. He partners with Dr Roger Glass, a diarrhoeal expert working then at the CDC's rotavirus laboratory. Around the same time, Dr Durga Dass discovers another strain, I321 at Indian Institute of Science (IISc), Bangalore. He collaborates with Dr Harry Green berg of Stanford University for further research.

â—„ **1987:** Both the naturally occuring, weakened strains studied by the two independent research teams working parallely under the Indo-US Vaccine Action Programme, bilateral program implemented since 1987 by DBT and NIH.

â—„ **2000:** Consortium of partners including Bharat Biotech, CDC, NIH, AIIMS, Stanford University, and IISc, submitted a proposal to PATH and DBT for support to move the two vaccine candidates through production, testing and surveillance.

â—„ **2003:** Partners meet to discuss the clinical studies strategies of the 116E and 1321 vaccine lots. After clearance of protocols for the phase I, first Indian trials began at AIIMS.

â—„ **2004-2005:** The trial results showed the 116E strain being more effective, providing immunity to 36.6 percent of recipients as compared to 15.4 percent of l321 recipients. On the basis of results, focus was completely put on 116E strain for further development.

â—„ **2006:** The consortium initiated combined phase Ib/IIa dose escalation study of the 116E vaccine candidate in infants at National Institute of Immunology, Delhi.

â—„ **2008:** The conclution of Phase Ib/IIa trial showed no identified safety concerns and demonstrated robust immune response in 89 percent of infants.

â—„ **2011:** The Phase III trials of 116E (now named Rotavac) on 6,799 infants began across three sites in India.

â—„ **2013:** The data from trial results presented at the international symposium on 'Rotavirus Vaccines for India- The Evidence and the Promise', showed Rotavac to have an excellent safety and efficacy profile.

The Indian efforts were led from the front by DBT, AIIMS, IISc equally supported by Translational Health Science and Technology Institute (THSTI) for laboratory testings. While Bharat Biotech invested important technical, manufacturing, and financial resources towards vaccine development, Quintiles was responsible for several aspects of the trial including medical monitoring, data management, site monitoring, pharmacovigilance, and biostatistics. The Good Clinical Practice compliance of the clinical trials was audited by ANTHA Clinical Quality Assurance. Apart from Indian partners, development partnership included the Bill and Melinda Gates Foundation, the Research Council of Norway, and the UK Department for International Development, the US National Institutes of Health (NIH), the US Centers for Disease Control and Prevention (CDC), Stanford University School of Medicine, and the nongovernmental organization, PATH.

Now, the positive results have made both the researchers and industry very confident about the indigenous efforts for other vaccine initiatives as well. While Dr Bhan also is of the opinion that it can serve as an inspiring story, the present DBT secretary, Dr K VijayRaghvan, too seems to be in full agreement when he says that this kind of partnership showcases the maturing Indian science and biomedical system. "The success of rotavirus vaccine initiative has added to India's know-how and capacity in ways that will pay dividends for the development of future solutions," added the DBT chief.