Rotavirus vaccine results declared 'encouraging' in phase-I trials
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THE INDIAN Rotavirus Vaccine Development Project (RVDP), supported by the Gates Foundation, has developed two rotavirus vaccines that have shown "encouraging" results in phase I clinical trials. These vaccine candidates, 116E and I321, represent the products of two independent research teams from RVDP. Rotavirus is the leading cause of severe diarrhoea in children and accounts for 400,000 hospitalisations and 160,000 deaths in India alone. The project is supported by the Gates Foundation, the Indo-US vaccine action programme and government of India's biotechnology department. Following the successful results in phase one, there are plans to begin clinical trials with cGMP vaccine lots produced by Hyderabad-based vaccine manufacturer Bharat Biotech. These trials are expected to begin in the second quarter of 2006, according to a statement. Bharat Biotech has successfully developed the 116E and I321 human rotavirus strains as vaccine candidates. These candidates have undergone extensive characterisation and quality control testing at Bharat Biotech and other external agencies with global standards.