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India approves Ph III trials of Biological E's COVID-19 vaccine candidate

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For active controlled Phase III clinical trial in adult population & Phase II/III paediatric trial in children and adolescents (5yrs and above)



Indian firm Biological E. has received Drugs Controller General of India (DCGI) approval for conducting Phase III Comparator Safety & Immunogenicity trial in adults after Subject Expert Committee's (SEC) review of Phase I and II clinical trials data of CORBEVAX.

Additionally, Biological E also received approval to initiate the Phase II/III Study to evaluate Safety, Reactogenicity, Tolerability and Immunogenicity of CORBEVAX vaccine in Children and Adolescents. The candidate is a RBD protein sub-unit vaccine.

The Department of Biotechnology (DBT) and its PSU, Biotechnology Industry Research Assistance Council (BIRAC) have supported Biological E's COVID-19 Vaccine candidate from Preclinical Stage to Phase III clinical studies.

In addition to receiving financial assistance under Mission COVID Suraksha, this vaccine candidate has also obtained a financial support under COVID-19 Research Consortia through National Biopharma Mission, BIRAC.