

DCGI approves Phase II/III clinical trial of COVAXIN in the age group of 2 to 18 Years

M/s Bharat Biotech to conduct trials in 525 healthy volunteers

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The National Regulator of the country, the Drugs Controller General of India (DCGI), after careful examination, has accepted the recommendation of Subject Expert Committee (SEC) and accorded permission to conduct the Phase II/III clinical trial of Covaxin (COVID vaccine) in the age group 2 to 18 years, to its manufacturer Bharat Biotech Ltd on 12.05.2021.

M/s Bharat Biotech International Ltd., Hyderabad (BBIL) had proposed to carry out a Phase- II/III clinical trial of Covaxin in the age group of 2 to 18 years. The trial will be conducted in 525 healthy volunteers.

In the trial, the vaccine will be given by intramuscular route in two doses at day 0 and day 28.

As rapid regulatory response, the proposal was deliberated in Subject Expert Committee (SEC) (COVID-19) on 11.05.2021. The Committee after detailed deliberation recommended for grant of permission to conduct proposed Phase II/III clinical trial to certain conditions.

MV/M

HFW/DGCI-Covaxin trial-2-18yrs/13thMay2021/2

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