

Bharat Biotech to conduct Ph II/III trial of Covaxin on under-18

13 May 2021 | News

The vaccine will be given by intramuscular route in two doses at day 0 and day 28



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.

Bharat Biotech will be carrying 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.