

## Serum Institute pursues early availability of Covishield vaccine in India

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**The strategic alliance between the SII and the ICMR will advance India's role in the global race to develop COVID-19 vaccines**



Serum Institute of India (SII) and Indian Council of Medical Research (ICMR) have announced completion of enrolment of phase 3 clinical trials for COVISHIELD in India. ICMR and SII have further collaborated for clinical development of COVOVAX (Novavax) developed by Novavax, USA and upscaled by SII. The partnership is a stellar example of private-public institutes collaborating to mitigate the dire consequences of the pandemic outbreak.

ICMR has funded the clinical trial site fees while SII has funded other expenses for COVISHIELD. At present, SII and ICMR are conducting Phase 2/3 clinical trial of COVISHIELD at 15 different centres, across the country. It has completed the enrolment of all 1600 participants on 31 Oct 2020.

COVISHIELD has been developed at the SII Pune laboratory with a master seed from Oxford University/Astra Zeneca. The vaccine made in UK is currently being tested in large efficacy trials in UK, Brazil, South Africa and USA. The promising results of the trials so far give confidence that COVISHIELD could be a realistic solution to the deadly pandemic.

COVISHIELD is by far the most advanced vaccine in human testing in India. Based on the Phase 2/3 trial results, SII with the help of ICMR will pursue the early availability of this product for India. SII has already manufactured 40 million doses of the vaccine, under the at-risk manufacturing and stockpiling license from DCGI.

Furthermore, US-based Novavax has initiated its late phase trials in South Africa and in UK and will soon commence the same in the USA. SII has received the bulk vaccine and Matrix-M adjuvant from Novavax and will soon fill and finish them in vials. This vaccine formulated at SII (COVOVAX) will be tested in a Phase 3 trial in India and an application for the same to regulatory authorities will be made soon by ICMR and SII.

Commenting on the association, Adar Poonawalla, CEO of Serum Institute of India, said, "ICMR has played a huge role in coming forward and strengthening India's fight against COVID-19. The collaboration will further aid us in putting India at the forefront of developing an immunogenic and efficacious vaccine. The pandemic has presented a chance to foster structural

reforms in building robust public healthcare infrastructure. The partnership further testifies the importance of private-public institutes coming together in scaling up the management and containing the spread of the virus.”

Dr. Balram Bhargava, Director General of Indian Council of Medical Research (ICMR), commented, “At present, India plays a prominent role in vaccine development and manufacturing globally. Buoyed by the latest technology and well-equipped facilities, SII has continually proven its research and manufacturing prowess. The partnership is our contribution to lending our expertise and support to bolster our fight against the global pandemic.”