

Novavax initiates COVID-19 vaccine clinical trial crossover

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Crossover ensures the administration of an active vaccine to all participants in the trials and has begun for Novavax's Phase 2b trial in South Africa and its pivotal Phase 3 trial in the UK



Novavax, Inc has announced the initiation of crossover arms in two ongoing clinical trials of NVX-CoV2373, the company's COVID-19 vaccine candidate. Crossover ensures the administration of the active vaccine to all participants in the trials and has begun for Novavax's Phase 2b trial in South Africa and its pivotal Phase 3 trial in the UK.

Under Novavax's updated clinical trial protocols, all participants in the UK and the US Phase 3 trials will be offered the opportunity to receive an additional round of injections. Participants who elect to do so will receive an additional two-dose regimen of either vaccine (for those who originally received placebo) or placebo (for those who originally received a vaccine).

Participants in the South Africa Phase 2b trial will receive either an active vaccine for those who initially received a placebo or a booster dose of an active vaccine for those who initially received the active vaccine.

Participants across all three trials will remain blinded to their courses of treatment to preserve the ability to assess efficacy in each trial, and all will be followed for up to two years to monitor the safety and durability of protection of the vaccine.

In the trials taking place in South Africa and the UK, half of the participants initially received the active vaccine while two-thirds of participants in PREVENT-19, the trial being conducted in the US and Mexico, initially received the active vaccine.

"The crossover arms ensure that all participants have access to an active vaccine candidate while allowing Novavax to continue to monitor the safety and efficacy of our vaccine over the long term," said Filip Dubovsky, Chief Medical Officer, Novavax.

The company is also planning a crossover in the PREVENT-19 study, for which the company expects to read out initial clinical data during the second quarter.