

# Novavax Statement on Updated PREVENT-19 Trial Protocol

May 10, 2021

An updated protocol version 8.0 for our PREVENT-19 Phase 3 clinical trial (the PRE-fusion protein subunit Vaccine Efficacy Novavax Trial) was posted to the Novavax website today. PREVENT-19 is a randomized, observer-blinded, placebo-controlled study evaluating the efficacy, safety, and immunogenicity of NVX-CoV2373 with Matrix-M™ adjuvant in up to 30,000 subjects 18 years of age and older compared with placebo. The company's pivotal Phase 3 study in the U.S. and Mexico began in December 2020 and significant progress has been made to-date, with final data expected in the second quarter of 2021.

PREVENT-19 was originally designed for an interim analysis after the accrual of 72 events and a final analysis after 144 events. Because of increasing availability of Emergency Use COVID-19 vaccines and public health recommendations for their use, a blinded crossover was initiated in April. The final analysis will be conducted on events accrued prior to participants receiving crossover vaccine. This design enables an evaluation of the safety and efficacy of the NVX-CoV2373 vaccine while maintaining the integrity of the blinded, controlled clinical trial.

To learn more, read the updated PREVENT-19 protocol version 8.0 [here](#).