

Novavax Statement on UK and Mexico Phase 3 Clinical Trial Participants Considered Fully Vaccinated in the US

November 10, 2021

The US Centers for Disease Control and Prevention (CDC) provided [updated guidance \(Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States\)](#) stating that Novavax clinical trial participants from sites outside the US are considered fully vaccinated if they received the same product that was administered and independently evaluated in the US clinical trials. This means that participants in the UK and Mexico Phase 3 clinical trials are considered fully vaccinated if they received the full series of active Novavax COVID-19 vaccine.

The CDC's travel guidance ([Technical Instructions for Implementing Presidential Proclamation Advancing Safe Resumption of Global Travel During the COVID-19 Pandemic and CDC's Order](#)) states that a person who received the full series of active Novavax COVID-19 vaccine meets the definition of a person who is "fully vaccinated against COVID-19." The guidance also includes details on establishing proof of vaccination. Novavax clinical trial participants can contact their trial sites if they have not yet received proof of vaccination.

Novavax is grateful to our clinical trial participants for helping to ensure a safer future for all, and we continue to advocate for them at the highest levels.

Novavax is preparing to submit the complete package for NVX-CoV2373, our protein-based COVID-19 vaccine to the US Food & Drug Administration (FDA) for emergency use authorization. The CDC guidance does not imply that the vaccine has been approved or authorized by FDA or is recommended by CDC or ACIP.