

September 17, 2021

Dear UK Phase 3 clinical trial participants,

Thank you for your continued participation in our study – we remain grateful for your commitment. We also appreciate your feedback and keep your experiences in mind as we strive with urgency to complete our work.

This message provides updates about our UK COVID-19 vaccine Phase 3 clinical trial as we approach Autumn.

Timing Update: Medicines and Healthcare products Regulatory Agency (MHRA) and other Regulatory Filings

Novavax is in active conversations with various regulatory agencies, including MHRA, EMA, WHO, FDA and others, and is working on the completion of our rolling submissions. Novavax is in alignment with these regulatory authorities on the final requirements to complete these submissions. As a result, there is additional work underway and we now expect that these final filings, including to MHRA, will occur in close proximity to each other in the next couple of months.

We understand that the revised timing for filing and potential authorization may extend certain challenges and frustrations for participants, and for that we sincerely apologize. We want you to know that we are doing everything we can to progress our work as rapidly as possible.

JCVI Booster Recommendation and Additional Doses of Deployed Vaccine

The United Kingdom's Joint Committee on Vaccination and Immunizations (JCVI) has provided [updated advice](#) on COVID-19 vaccine booster doses and we are aware that some participants may now be eligible to receive booster doses of approved vaccines. We are also aware that some trial participants have sought to receive two doses of a deployed vaccine, after having had two doses of the Novavax vaccine.

At this time, Novavax cannot provide guidance on the safety of receiving either two doses or a single booster of an approved vaccine after having previously received two doses of the Novavax vaccine. This is because data to support such advice does not exist. We have sought urgent guidance from NHS/JCVI, which they are actively considering. We appreciate your patience as we continue to work with authorities and encourage you to speak to your trial team or GP if you have questions.

Booster Study

Given the dynamic vaccination landscape, we continue to explore the potential for a booster study in the UK. The lead investigator at your site will inform you about any future booster studies. In the meantime, we ask participants to continue in the trial that will finish as planned, at approximately 12 months after the date of the second (pre-crossover) dose of vaccine/placebo. Your study team will be in touch to schedule end-of-study visits.

Proof of Vaccination

We know that proof of vaccination status as a trial participant may not be recognized everywhere. The UK government and Novavax continue to make the case internationally and advocate, based on documented Phase 3 safety and efficacy data, that those who participate in a COVID-19 vaccine trial should be considered vaccinated just as those who receive a deployed vaccine. Novavax will continue to support efforts to ensure trial participants are accepted as fully vaccinated outside the UK.

Again, we are sorry for any difficulties and frustrations that you have encountered. Vaccine development is highly complex and often requires years to advance to the point we are now. This work is simply taking longer than any of us wants, and we are progressing our filing as rapidly as possible. Thank you again for your participation and your patience.

Sincerely,

Filip Dubovsky, M.D.
Executive Vice President, Chief Medical Officer, Novavax