
J&J's Vaccine Trial Paused



Johnson & Johnson has [announced](#) temporarily pausing the COVID-19 vaccine candidate trials due to an unexplained illness in a study participant.

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As reported by STAT News, the company has informed external researchers through a document that a “passing rule” has been met and the patient enrolment is not available for the time being. “We have temporarily paused further dosing in all our COVID-19 vaccine candidate clinical trials, including the [Phase 3 ENSEMBLE](#) trial, due to an unexplained illness in a study participant,” the company said in the statement noting that “the participant’s illness is being reviewed and evaluated by the ENSEMBLE independent Data Safety Monitoring Board (DSMB) as well as our internal clinical and safety physicians”. According to STAT News, DSMB convened on 12 October to review the case.

J&J explained that a study pause, in which recruitment or dosing is paused by the study sponsor, is a standard component of a clinical trial protocol, and while the study investigators are informed about such events, it is not typically communicated to the public as a clinical hold would be, which is a formal regulatory action.

The company [started to recruit](#) participants for the Phase 3 trial late September, aiming to enrol up to 60,000 volunteers across more than 200 sites in countries such as the US, Argentina, Brazil, Chile, Colombia, Mexico, Peru and South Africa. The research is funded by the US National Institutes for Health (NIH).

J&J has become the 10th manufacturer globally to conduct a Phase 3 COVID-19 vaccine candidate trial.

While study pauses are not uncommon, currently they are drawing a lot of attention considering the importance of the COVID-19 vaccine testing. In addition, another large study, by AstraZeneca and Oxford University, was halted on 8 September because of a suspected adverse reaction in a patient. It has since then been [resumed](#) (after about a week’s time) in the UK, but is still on hold in the US.

Source: [Stat News](#)

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