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J&J temporarily halts COVID-19 vaccine trial

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Due to an unexplained illness in a study participant



American multinational firm Johnson & Johnson has temporarily paused further dosing in all COVID-19 vaccine candidate clinical trials, including the Phase 3 ENSEMBLE trial, due to an unexplained illness in a study participant.

Following the guidelines, 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.

Adverse events – illnesses, accidents, etc. - even those that are serious, are an expected part of any clinical study, especially large studies.

As stated by the company, "A **study pause**, in which recruitment or dosing is paused by the study sponsor, is a standard component of a clinical trial protocol. As noted in the ENSEMBLE study protocol, Johnson & Johnson has robust mechanisms in place to protect the safety of participants in its clinical trials. While the company informs all study investigators, we typically do not communicate study pauses publicly."

The company has also stated that, "We must respect this participant's privacy. We're also learning more about this participant's illness, and it's important to have all the facts before we share additional information."