



With regard to reports of a death in Phase III trials, we would like to state that a volunteer passed away on December 21, 2020 and the death was reported to the People's College of Medical Sciences & Research Centre by the son of the deceased. The volunteer, at the time of enrolment, had fulfilled all the inclusion and exclusion criteria to be accepted as a participant in the Phase III trial and was reported to be healthy in all the site follow up calls post 7 days of his dosing and no AE's were observed or reported. As per the post-mortem report issued by the Gandhi Medical College, Bhopal that the site received from the Bhopal Police, the probable cause of death was due to cardio respiratory failure as a result of suspected poisoning and the case is under police investigation as well. The volunteer passed away nine days after the dosing and preliminary reviews by the site indicate that the death is unrelated to the study dosing. We cannot confirm if the volunteer received the study vaccine or a placebo as the study is blinded.

In accordance with the provisions of the New Drugs & Clinical Trials Rules, (NDCT rules 2019) the serious adverse event was reported by the site team to the Institutional Ethics Committee, the Central Drugs Control Standards Organization (CDSCO) and the Data Safety Monitoring Board (DSMB) in accordance to all the required guidelines. There are several factors that can cause an adverse event during a clinical trial, including the patient's underlying disease, other pre-existing conditions or any other unrelated occurrence like an accident. The NDCT rules mandate that all adverse events (AE) and serious adverse events (SAE) be reported, whether related to the trial medication or not. This SAE has been thoroughly investigated and has been found not related to vaccine or placebo. All data and reports on this SAE have been submitted to Site Ethics Committee, CDSCO and DSMB. We are also continuing to cooperate with the investigation requirements from the Madhya Pradesh Police in Bhopal.

Our sympathies are with the family of the deceased. However, we would like to reiterate that we conduct our clinical trials in compliance with the study protocol, Good Clinical Practices (GCP) Guidelines as well as with all applicable statutory provisions and the focus at all times is on patient safety. It is this intent on compliance, quality and ethics, that we have enlisted the services of an international contract research organization to conduct our phase III clinical trials.

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