

Subject: SAE Reporting Note – Subject No: 07/5119/029

Protocol Title: Randomised phase II trial testing efficacy of intra-tumoural hydrogen peroxide a radiation sensitiser in patients with locally advanced/recurrent breast cancer - CCR5119 KORTUC

CTRI Regd. No: CTRI/2022/02/040331

Note on Reporting Timeline and IRB Discussion:

This note is to formally document the reporting status of the Serious Adverse Event (Grade V - Death due to Myocardial Infarction) concerning **Subject No: 07/5119/029**, which occurred on 29-Mar-2026 and was notified to the IRB on 22-Apr-2026.

Please be advised that a detailed review of this SAE is on the agenda and scheduled to be discussed in the upcoming **110th IRB Meeting**. However, in order to strictly comply with the 30-day regulatory time restraint for reporting fatal SAEs, we are submitting this report now. This expedited submission is being made following formal discussions with the Ethics Committee (EC).

As outlined in the attached SAE report, the preliminary consensus from the SAE subcommittee and the IRB is that the event is unlikely to be related to the trial intervention. The patient had documented disease progression and transitioned to palliative care prior to the event; therefore, the cause of death was deemed to be Acute Coronary Syndrome (ACS) secondary to progressive disease. Accordingly, no financial compensation for medical management is recommended.