

Subject: SAE Reporting Note – Subject No: 07/5119/023

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 III - Abdominal Distension) concerning **Subject No: 07/5119/023**, which occurred on 19-Apr-2026 and was successfully resolved on 20-Apr-2026 following inpatient supportive care.

Please be advised that a detailed review of this SAE is currently 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 Serious Adverse Events, 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 unrelated to the trial intervention. The patient was enrolled in the standard arm and required brief hospitalization for symptom management (therapeutic ascitic tapping and IV administration). The patient was discharged in a stable condition the following day. Accordingly, no financial compensation for medical management is applicable.