

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.

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

Subject No: 07/5119/023

Date of Onset: 19 Apr 2026

Date of Resolution: 20 Apr 2026

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

Adverse Event: Abdominal Distension

Causality: Unrelated to the trial intervention

Outcome: Resolved/ Discharged

Severity: Grade III

Brief History:

- 13-SEP-2024: Completed palliative radiotherapy (36 Gy in 6 fractions) to the left breast under the standard arm initiated on 27-AUG-2024.
- 19-APR-2026:
 - Admitted under the Medical Oncology team for management of abdominal distention, nausea, constipation, and left lower limb swelling.
 - Underwent bilateral lower limb USG Doppler, which ruled out deep vein thrombosis (DVT) and identified mild diffuse subcutaneous edema.
 - Performed therapeutic ascitic tapping and administered intravenous Human Albumin and Metoclopramide as part of the inpatient supportive care regimen.
- 20-APR-2026: Discharged in stable condition following clinical stabilization and symptomatic relief.

SAE subcommittee decision:

- **Time relationship:** Appropriate
- **Competing Causes:** None
- **De-Challenge/ Re-challenge:** NA
- **WHO-UMC Causality:** Unlikely

IRB Decision: The patient was in the standard arm. It is unlikely that the current SAE is related to the trial intervention.

Financial compensation: Not Applicable for compensation and medical management

IRB

From: Partha Majumder <parmaj2023@gmail.com>
Sent: 05 May 2026 12:48
To: IRB
Subject: Re: Decision regarding KORTUC SAE- Participant number 023-Other than Death

CAUTION: This email originated from outside of the organisation. Do not click links or open attachments unless you recognize the sender and know the content is safe. This is to safeguard yourself against phishing attacks.

Since the SAE occurred in a patient who was in the standard arm, I concur with the view that the SAE is unrelated to the trial.

=====

PARTHA P. MAJUMDER, PhD, FNA, FASc, FNASc, FTWAS

Distinguished Professor, John C. Martin Centre for Liver Research & Innovations

Emeritus Professor, Indian Statistical Institute, Kolkata

Adjunct Faculty Member, Indraprastha Institute of Information Technology Delhi

Council Member, Human Genome Organisation

Member of Technical Advisory Groups on 'Genomics' and 'AI & Health', World Health Organization

Formerly (7/2020-6/2025) *National Science Chair*, Government of India

Founder, National Institute of Biomedical Genomics

INDIA

Email addresses: parmaj2023@gmail.com [Preferred] OR ppm@isical.ac.in

- **Homepage:** <https://ppmonweb.github.io/>

On Mon, May 4, 2026 at 12:37 PM IRB <irb@tmckolkata.com> wrote:

Respected members,

A Severe Adverse Event (SAE) resulting in death has been recorded for Subject No: 07/5119/023 under the CCR5119 KORTUC trial (CTRI Regd. No: CTRI/2022/02/040331).

Brief summary of the event based on the recent SAE subcommittee and IRB review:

- Adverse Event: Abdominal Distention

- Outcome: Death (Severity: Grade III)
- Date of Onset 19 Apr 2026
- Date of Resolution: 20 Mar 2026
- Causality: Unlikely to be related to the trial intervention
- IRB Decision: The patient was in the standard arm. It is unlikely that the current SAE is related to the trial intervention

Requesting you to share your response at the earliest by 48 Hours

Sincerely

Arkendra Narayan Choudhury

IRB Secretary

Tata Medical Center, Kolkata 700160

IRB

From: Ivan Satyavrata <ivan.satyavrata@gmail.com>
Sent: 04 May 2026 17:21
To: IRB
Cc: IRBgroup
Subject: Re: Decision regarding KORTUC SAE- Participant number 023-Other than Death

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Support & endorsement of the SAE subcommittee's recommendation.

Ivan Satyavrata

On 4 May 2026, at 7:37 AM, IRB <irb@tmckolkata.com> wrote:

Respected members,

A Severe Adverse Event (SAE) resulting in death has been recorded for Subject No: 07/5119/023 under the CCR5119 KORTUC trial (CTRI Regd. No: CTRI/2022/02/040331).

Brief summary of the event based on the recent SAE subcommittee and IRB review:

1. Adverse Event: Abdominal Distention
2. Outcome: Death (Severity: Grade III)
3. Date of Onset 19 Apr 2026
4. Date of Resolution: 20 Mar 2026
5. Causality: Unlikely to be related to the trial intervention
6. IRB Decision: The patient was in the standard arm. It is unlikely that the current SAE is related to the trial intervention

Requesting you to share your response at the earliest by 48 Hours

Sincerely

Arkendra Narayan Choudhury

IRB Secretary
Tata Medical Center, Kolkata 700160

<KORTUC 023- Other than Death.pdf>

The Drugs Controller General (India)

The Directorate General of Health Services; Ministry of Health and Family Welfare; Government of India

FDA Bhawan, Kotla Road; New Delhi – 110 002

Subject: Report of Serious Adverse Event (SAE) of injury under the clinical trial protocol No: KORTUC Protocol-Regarding:

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

Subject No: 07/5119/023

Date of Onset: 19 Apr 2026

Date of Resolution: 20 Apr 2026

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

Adverse Event: Abdominal Distension

Causality: Unrelated to the trial intervention

Outcome: Resolved/ Discharged

Severity: Grade III

Brief History:

☐ 13-SEP-2024: Completed palliative radiotherapy (36 Gy in 6 fractions) to the left breast under the standard arm initiated on 27-AUG-2024.

☐ 19-APR-2026:

o Admitted under the Medical Oncology team for management of abdominal distention, nausea, constipation, and left lower limb swelling.

o Underwent bilateral lower limb USG Doppler, which ruled out deep vein thrombosis (DVT) and identified mild diffuse subcutaneous edema.

o Performed therapeutic ascitic tapping and administered intravenous Human Albumin and Metoclopramide as part of the inpatient supportive care regimen.

☐ 20-APR-2026: Discharged in stable condition following clinical stabilization and symptomatic relief.

SAE subcommittee decision:

☐ Time relationship: Appropriate

☐ Competing Causes: None

☐ De-Challenge/ Re-challenge: NA

☐ WHO-UMC Causality: Unlikely

IRB Decision: The patient was in the standard arm. It is unlikely that the current SAE is related to the trial intervention.

Financial compensation: Not Applicable for compensation and medical management

Sincerely,



Dr Indranil Mallick

Member Secretary;

Institutional Review Board; Tata Medical Center; Kolkata 700160