

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.

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: 07/5119/029

Date of Onset: 29 Mar 2026

Date of Death: 29 Mar 2026 [Notified to IRB on 22 Apr 2026]

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

Adverse Event: Myocardial infarction

Causality: Unlikely to be related to the trial intervention

Outcome: Death

Severity: Grade V

Brief History:

- **20-SEP-2025:**
 - Completed palliative radiotherapy (36 Gy in 6 fr) for metastatic carcinoma of the left breast.
 - Exemestane therapy initiated following documented disease progression during the post- radiotherapy surveillance period.
- **15-MAR-2026:** Transitioned to best supportive care under a palliative team due to escalating respiratory distress and a significant decline in performance status, which precluded further active oncological intervention.
- **29-MAR-2026:** The patient passed away at 06:05 AM; the immediate cause of death recorded on the death certificate by local physician > acute coronary syndrome.
- **06-APR-2026:** Trial site notified of the patient's death. The delay in reporting was due to the family not proactively informing the study team at the time of the event.

SAE subcommittee decision:

- **Time relationship:** Appropriate
- **Competing Causes:** Disease progression
- **De-Challenge/ Re-challenge:** NA
- **WHO-UMC Causality:** unlikely to be related to trial

IRB Decision: The patient had further disease progression and likely died as a result of the progressive disease. The cause of death was deemed to be ACS. No compensation is recommended.

Financial compensation: Not Applicable for compensation and medical management

IRB

From: Partha Majumder <parmaj2023@gmail.com>
Sent: 05 May 2026 12:50
To: IRB
Subject: Re: Decision regarding KORTUC SAE- Participant number 029- 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.

In view of the explanation provided by the SAE sub-committee, I support the conclusion 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 12:33 PM IRB <irb@tmckolkata.com> wrote:

Respected members,

A Severe Adverse Event (SAE) resulting in death has been recorded for Subject No: 07/5119/029 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: Myocardial infarction (Acute Coronary Syndrome)
- Outcome: Death (Severity: Grade V)
- Date of Onset / Death: 29 Mar 2026
- Causality: Unlikely to be related to the trial intervention
- IRB Decision: The patient had further disease progression and likely died as a result of the progressive disease. No compensation is recommended.

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 17:20
To: IRB
Cc: IRBgroup
Subject: Re: Decision regarding KORTUC SAE- Participant number 029- 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.

Support & endorsement of the SAE subcommittee's recommendation.

Ivan Satyavrata

On 4 May 2026, at 7:33 AM, IRB <irb@tmckolkata.com> wrote:

Respected members,

A Severe Adverse Event (SAE) resulting in death has been recorded for Subject No: 07/5119/029 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: Myocardial infarction (Acute Coronary Syndrome)
2. Outcome: Death (Severity: Grade V)
3. Date of Onset / Death: 29 Mar 2026
4. Causality: Unlikely to be related to the trial intervention
5. IRB Decision: The patient had further disease progression and likely died as a result of the progressive disease. No compensation is recommended.

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

Sincerely

Arkendra Narayan Choudhury

IRB Secretary
Tata Medical Center, Kolkata 700160

<KORTUC 029- 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 sensitizer in patients with locally advanced/recurrent breast cancer- CCR5119 KORTUC

Subject No: 07/5119/029

Date of Onset: 29 Mar 2026

Date of Death: 29 Mar 2026 [Notified to IRB on 22 Apr 2026]

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

Adverse Event: Myocardial infarction

Causality: Unlikely to be related to the trial intervention

Outcome: Death

Severity: Grade V

Brief History:

- ☐ 20-SEP-2025:
 - o Completed palliative radiotherapy (36 Gy in 6 fr) for metastatic carcinoma of the left breast.
 - o Exemestane therapy initiated following documented disease progression during the post- radiotherapy surveillance period.
- ☐ 15-MAR-2026: Transitioned to best supportive care under a palliative team due to escalating respiratory distress and a significant decline in performance status, which precluded further active oncological intervention.
- ☐ 29-MAR-2026: The patient passed away at 06:05 AM; the immediate cause of death recorded on the death certificate by local physician > acute coronary syndrome.
- ☐ 06-APR-2026: Trial site notified of the patient's death. The delay in reporting was due to the family not proactively informing the study team at the time of the event.

SAE subcommittee decision:

- ☐ Time relationship: Appropriate
- ☐ Competing Causes: Disease progression
- ☐ De-Challenge/ Re-challenge: NA
- ☐ WHO-UMC Causality: unlikely to be related to trial

IRB Decision: The patient had further disease progression and likely died as a result of the progressive disease. The cause of death was deemed to be ACS. No compensation is recommended.

Financial compensation: Not Applicable for compensation and medical management

2. Indicate with justification and documentary evidence as to whether the SAE (injury) is related/not related to each of the following criteria:

- Adverse effect of investigational product(s): No
- Violation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or investigator: No
- Failure of investigational product to provide intended therapeutic effect [where the standard care, though available, was not provided to the subject as per the clinical trial protocol]: No
- Use of placebo in a placebo-controlled trial [where, the standard of care, though available, was not provided to the subject as per the clinical trial protocol]: No
- Adverse effect due to concomitant medication excluding standard of care necessitated as part of approved protocol: No
- For injury to a child in-utero because of the participation of present in clinical trial: No
- Any clinical trial procedure involved in the study: No

3. Risk Factor Assessment (0.5 to 4) as per the compensation formula decided by IEC: NA

Sincerely,

Dr Indranil Mallick

Member Secretary;

Institutional Review Board; Tata Medical Center; Kolkata 700160