

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

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In view of the explanation provided by the SAE sub-committee, I support the conclusion that the SAE is unrelated to the trial.

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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