

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>