

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

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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.

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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