

DSMB REPORT



Grant Title:

Empirical treatment against cytomegalovirus and tuberculosis in severe pneumonia in HIV-infected infants: a randomized controlled clinical trial

EDCTP Grant reference number: **RIA2017MC-2013**

Project Acronym: **EMPIRICAL**

Dear Investigator,

Re: Data and Safety Monitoring Board (DSMB) meeting to review safety data

I am writing to inform you that on **February 1, 2021**, the external Data and Safety Monitoring Board (DSMB) conducted a scheduled meeting to review safety data from the above-mentioned study. During the meeting the EMPIRICAL Central Management Team has provided all data available by that day.

The DSMB identified no safety signals in their review and recommended that the EMPIRICAL study to continue without modification.

The Interim Analysis will be conducted in **January 2022**. The results will be shared with the corresponding authorities.

Please submit this communication to your respective institutional review board (IRB)/ethics committee.

Prof. Elizabeth Obimbo.
Chair, DSMB Empiric Study
Professor of Paediatrics, University of Nairobi
Date: 10th March 2021
Place: Nairobi, Kenya

Signature