



## EASTLAND CLINICAL TRIAL UPDATE

Eastland's Board is pleased to provide you with the following update from the African ART004 Clinical Trial titled,

“A Phase III, randomized, open labelled, active controlled, multi-centre, superiority trial of ArTiMist™ versus intravenous quinine in children with severe or complicated falciparum malaria, or uncomplicated falciparum malaria with gastrointestinal complications.”

The trial is powered around the enrolment and treatment of 150 patients.

- **Rwanda:** Status: Closed. Allocated 50 patients. 51 patients enrolled. All have completed treatment.
- **Burkina Faso:** Status: Open. Allocated 50 patients. 41 patients enrolled. Actively enrolling patients. After a slow start to the malaria season this site is enrolling patients rapidly with only 11 patients left to be enrolled and they are on track to finalise enrolment in the current malaria season.
- **Ghana:** Status: Open. Allocated 50 patients. 12 patients enrolled. Actively enrolling patients. The rains were late arriving to Ghana but have now set in with the malaria season now well underway. Ghana enrolled their initial 5 patients and a clinical audit of the data has now been carried out by our contractors. This audit is standard practice and is carried out to ensure that the clinical trial is being run as per the procedures set out in the clinical protocols. The auditors have confirmed that the Ghana site is following the correct procedures and is compliant. Ghana has been given permission to complete enrolment and has now enrolled 12 patients and is on track to complete the enrolment of the final 38 patients during the current malaria season.
- **Tanzania:** Status: Awaiting final approval. There have been major delays in the regulatory process in Tanzania and as ProtoPharma (lead Contractor) is unable to determine when this site will open, they have increased the number of patients in Burkina Faso and Ghana to compensate for the loss of patients in Tanzania. There will be no negative effect from the non-initiation of Tanzania. If Tanzania is approved prior to the completion of the patient enrolment ProtoPharma will review the patient requirements and make the appropriate decisions at that point in time.

We will provide further updates as they are received.

**Further information:**

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