Clinical Trial Sponsorship
WANECAAM Experience

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Clinical Trial Sponsorship Experience

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Clinical Trials Networking Capacity Building Clinical Trials
Study Title

A Phase IIIb/IV comparative, randomised, multicentre, open label, parallel 3-arm clinical study to assess the safety and efficacy of repeated administration of pyronaridine-artesunate, dihydroartemisinin-piperaquine or artemether-lumefantrine or artesunate-amodiaquine over a two-year period in children and adult patients with acute uncomplicated *Plasmodium* sp. malaria.
Study SPONSOR!
Definitions

• A **sponsor** is an individual, institution, company or organization (for example, a contract research organization) that takes the responsibility to initiate, manage or finance the **clinical trial**, but does not actually conduct the investigation.

http://www.marsdd.com/mars-library/
Responsibilities of the Sponsor

• Selecting the investigator(s)
• Providing investigator(s) with the necessary information to conduct the clinical trial
• Ensuring proper monitoring of the clinical study
• Ensuring all the necessary ethic review(s) and approval(s) are obtained
• Preparing and submitting clinical trial application(s) and amendment(s) to the appropriate regulatory agencies
• Ensuring that any reviewing ethics board and regulatory agencies are promptly informed of any significant new information (for example, important findings that affect product safety) in a clinical study
• Ensuring compliance with labelling, reporting and record-keeping requirements
• Refraining from engaging in promotional activities and other prohibited activities such as commercializing an investigational medical device
• Ensuring that the clinical study is conducted in accordance with Good Clinical Practice (GCP)
**Sponsor-investigator**

- Takes on the responsibility as a clinical study sponsor and *also* conducts or oversees the clinical trial.
- Thus, a sponsor-investigator must comply with the applicable regulatory requirements that pertain to both the sponsor and the investigator.
USTTB

Chancellor’s Office

Department of Research

Grantee

Sponsor

CRO
Sponsorship challenges

• Legal
• Regulatory
• Responsibilities
• Day to day operations
• Budgeting
• Oversight
Conclusion

• Need to develop capacity for Trial Sponsorship in Africa
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• WANECAM collaborators

• MRC Gambia
  – Jenny & Vivat

• USTTB, Bamako, Mali

• WANECAM Trial Partners
Acknowledgements
Clinical trials: Study investigator responsibilities

• Protecting the rights, safety and welfare of subjects in the clinical study
• Ensuring that informed consent is properly obtained from clinical trial subjects
• Conducting the clinical study (that is, directly overseeing the administration of the test products to the subject). In situations where there is a team of researchers, the investigator will act as the team leader
• Ensuring that the clinical trial is conducted in accordance with the signed agreement and the investigational plan
• Controlling the products under investigation (for example, supervising medical-device use and disposal)
• Ensuring proper record-keeping and reporting requirements are met (for example, mandatory safety reporting)