EDCTP Stakeholder Meeting on Capacity Development

Thursday, 3 July 2014

Berlin, Germany

Clinical Trial Sponsorship
WANECAM Experience

Abdoulaye Djimde

USTTB, Bamako, Mali

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Abdoulaye Djimde, PharmD, PhD

Project Coordinator

University of Science and Technology

Bamako, Mali


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Polska
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Україна
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Bay of
Biscay
România
Italia
España
Ελλάς
Türkiye
Portugal
Mediterranean
Sea
Tunisia
Syria
Iraq
Iran
Morocco
Algeria
Libya
مصر
Western
Sahara
Saudi
Arabia
Oman
Mauritania
Niger
Chad
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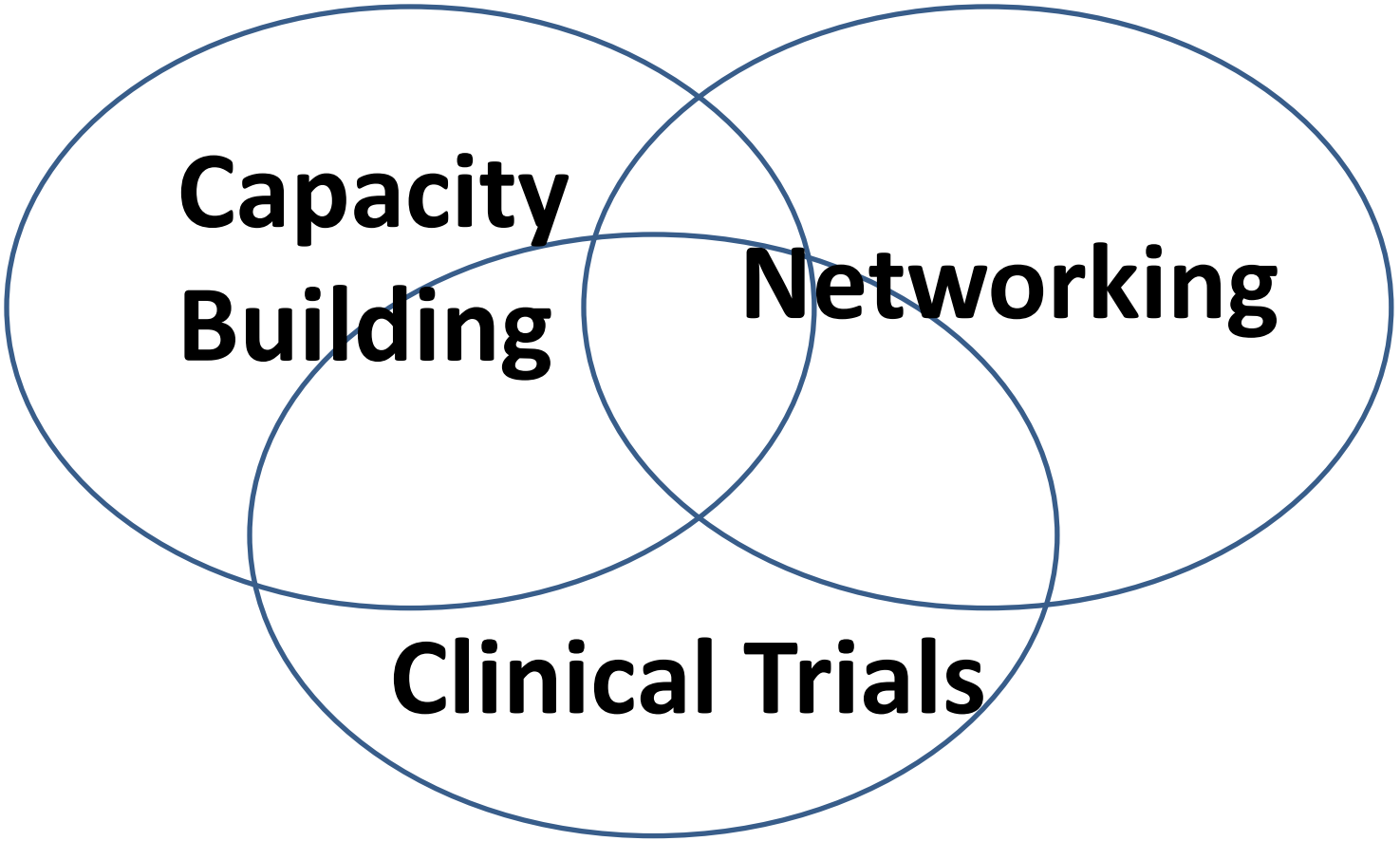
South
Sudan
Ethiopia
Gulf of
Guinea
Somalia
Kenya
Gabon
DR Congo


Capacity Building
Networking
Clinical Trials

West African Network for Clinical Trials of Antimalarial Drugs

Study Title

EDCTP

A Phase IIIb/IV comparative, randomised, multi-centre, 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.

Medicines for Malaria Venture
A nonprofit Foundation

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/

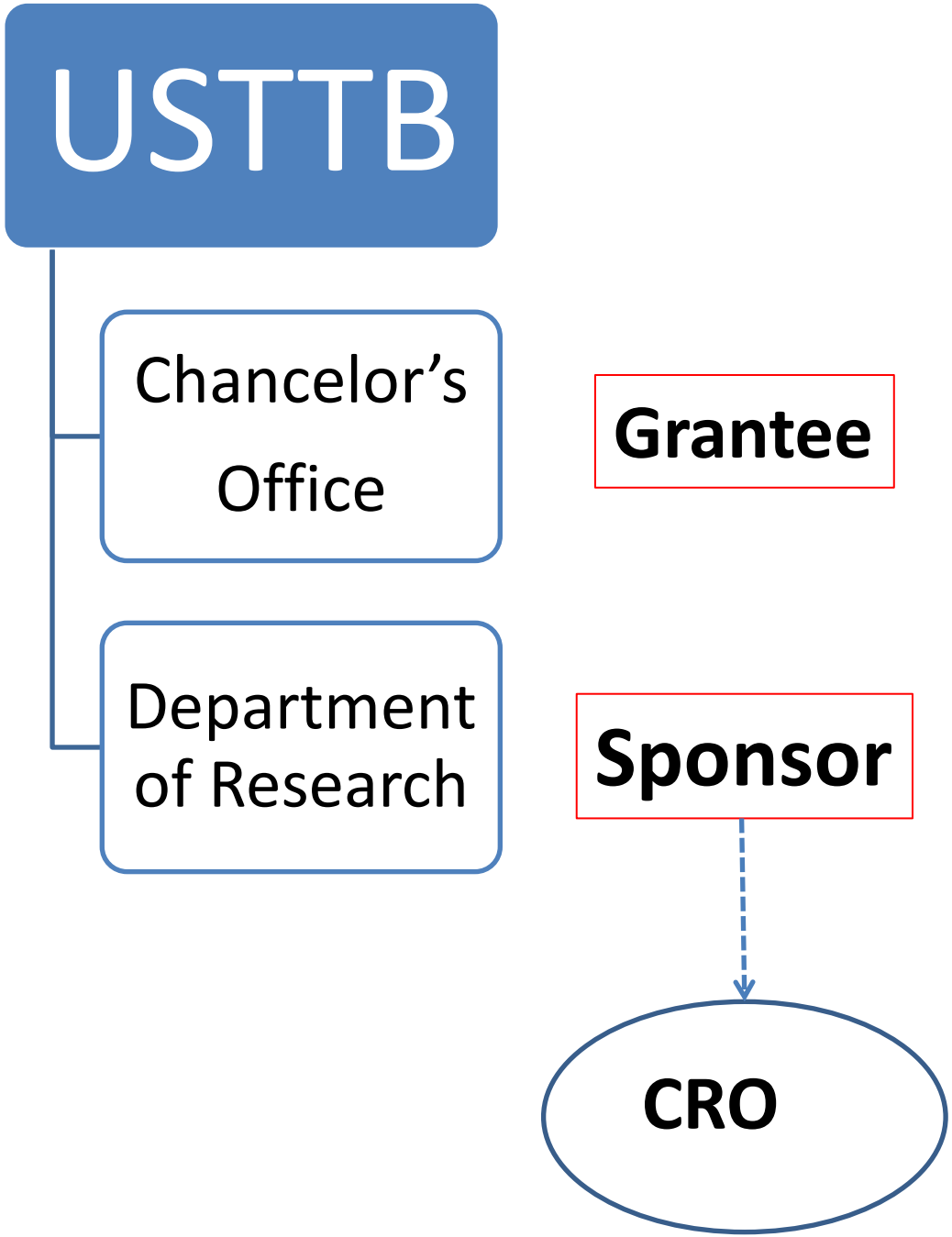
Responsibilities of the Sponsor

- 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)

WANECAM WORKSHOP MRC GAMBIA

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
Chancelor'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

Acknowledgements

- WANECAM collaborators
- MRC Gambia
  - Jenny & Vivat
- USTTB, Bamako, Mali
- WANECAM Trial Partners

Acknowledgements

MMV
Medicines for Malaria Venture

EDCTP
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The European Union

WANECAM
West African Network for Clinical Trials of Antimalarial Drugs

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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)