30 June – 2 July 2014

Seventh EDCTP Forum

The Partnership journey: New horizon for better health

Berlin, Germany

Réseau Ouest-Africain pour le développement des Médicaments Antipaludiques (ROAMA)

WANECAM

West African Network for Clinical Trials of Antimalarial Drugs

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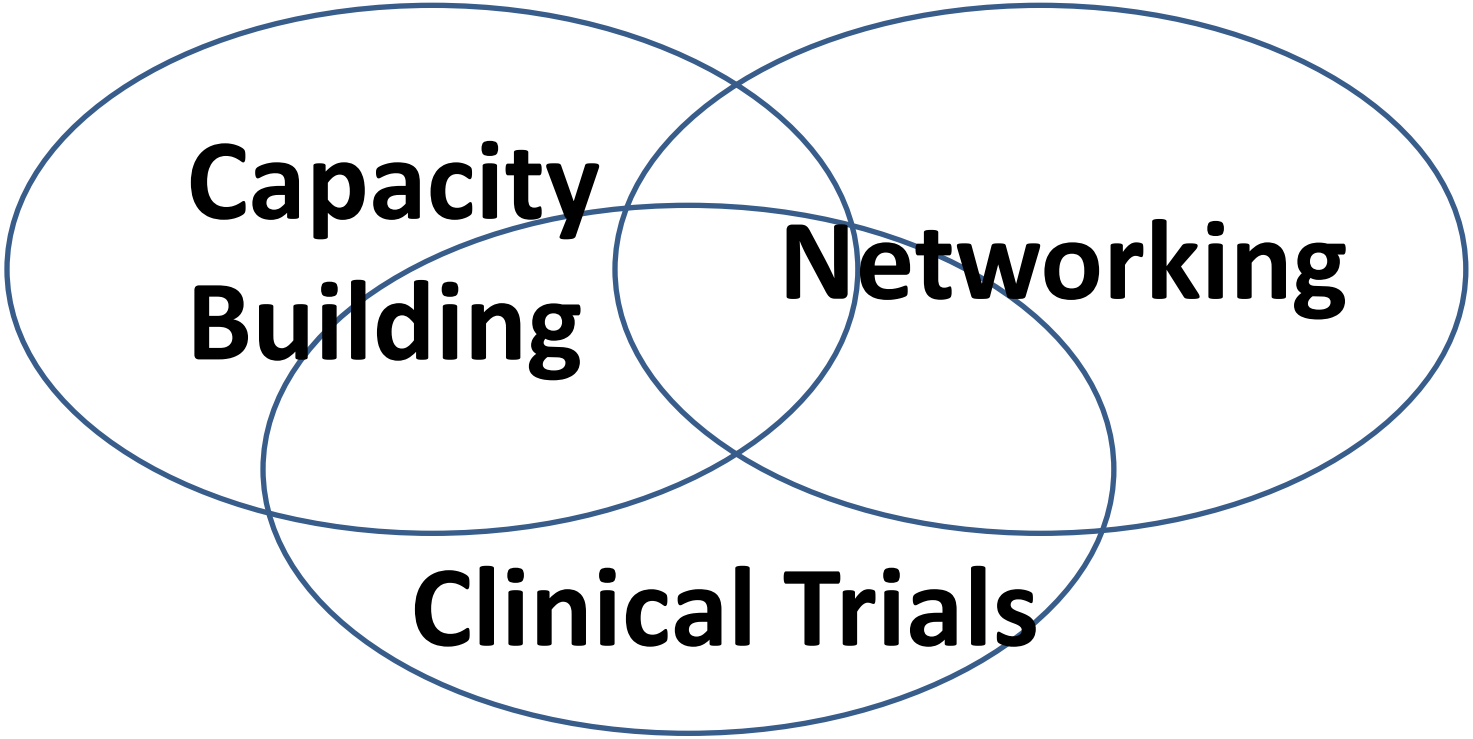

Capacity Building
Networking
Clinical Trials

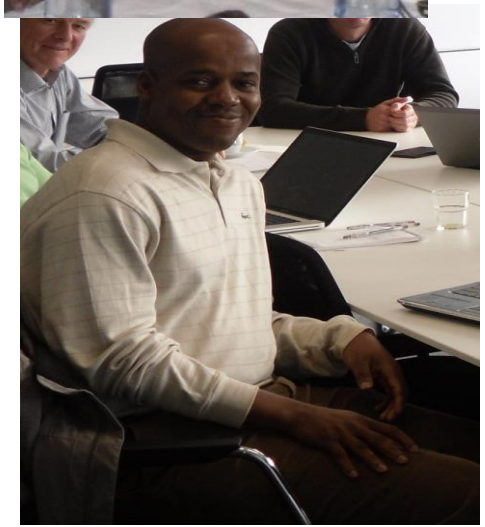
Capacity Building

- Training
  - PhD
  - MSc
  - Short term
- Infrastructure
- Environment
  - Financial
  - Administrative
  - Regulatory (GCP, GLP, Ethics)

Degree Training

- 3 PhDs (Sweden, Germany, France)
- 3 MSc (+2 additional MScs)
  - 2 Guinea (to Mali & Bobo)
  - 1 Burkina Faso (to Vienna)
  - 2 Mali - to Bobo Djoulasso

WANECAM MSc and PhD STUDENTS



Short term trainings

- GCP
- GCLP
- Financial procedures
- Ethics

Whorkshops

Dr SYLLA Malik Minkael
Dr COULIBALY Sam Abdoucar
Dr TRAORE Abdoulaye
SE. TIENDREBEOGO Gérard

Training in Financial procedures

Infrastructure Development

ViaSat

Networking

MINISTERE DE LA SANTE
SECRETARIAT GENERAL
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CLINIQUE DE BANFORA

North-South & South-North Students exchange

German student in Bobo Djoulasso, BF

U.K. student at the MRTC, Mali

Clinical Trials

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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

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Project Overview

- Investigator Initiated and led Study
- EMA require repeat dosing data on Pyramax for label extension
- Emphasis changed to producing high quality data for regulatory submission.

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Patient recruiting sites

EDCTP

Medicines for Malaria Venture
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Efficacy Endpoints

Primary endpoint:

- To compare the incidence rate of uncomplicated malaria in children and adults treated with repeated ACT therapy over a 2 year observation period

Secondary efficacy endpoints:

- PCR corrected and uncorrected ACPR at D28 and D42 (WHO definitions 2009)
- Re-infection and recrudescence rates over 42 days (KM survival analysis)
- FCT, PCT
- Gametocytes carriage and density
- Difference in time to the second infection between treatments
- Difference in the mean interval between re-infections

Safety endpoints

- Incidence of adverse events graded by severity including clinically significant laboratory results
- ECG abnormalities
- Vital signs or physical examination abnormalities
- Changes in biochemistry (including liver enzymes)
- Changes in haematology (specifically Hb and neutrophils)
- Neurological assessments

Exploratory endpoints

- PCR corrected and uncorrected at D63 (only in Bougoula Hameau, Mali)
- Gametocytes infectivity
- PK on day 7
- PK corrected cure rate
- Pharmacogenetics
- *PCR-based Parasite Clearance Time*

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Wanecam Study Timelines

EDCTP

- Study enrolment started FPFV 24-Oct-11
- Enrolment completed LPI 17-Dec-13
- Last patient's last visit LPO 17-Dec-15
- First results available (estimate) July 2016

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A Sub study to support a Pyramax Tablet label variation filing

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EDCTP

Total number of patients in the Study

(N=4722)

DHA-PQP

N=1344

PA

N=1344

ASAQ/AL

N=2034

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Next steps

- **Study is ongoing**
- **Numerous exciting results expected**
- **Completion estimated for December 2015**

- **Several hurdles to overcome !**

Acknowledgements

MMV
Medicines for Malaria Venture

EDCTP
Funded by the European and Developing Countries Clinical Trials Partnership
The European Union

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Acknowledgements

- MRTC, USTTB, Bamako, Mali
- CNRFP, Ouagadougou, Burkina Faso
- IRSS, Bobo Dioulasso, Burkina Faso
- CNFRSR, Mafèrinyah, Guinée
- MRC Gambia, The Gambia
- URM, Université Claude Bernard, Lyon, France
- MRU, Karolinska Institutet, Stockholm, Sweden
- LSHTM, London, United Kingdom
- MEMG, University of Heidelberg, Heidelberg, Germany

All study communities, field teams

Respectives Governments

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