KWAME NKRUMAH
UNIVERSITY OF SCIENCE AND TECHNOLOGY

KUMASI CENTRE FOR COLLABORATIVE RESEARCH IN TROPICAL MEDICINE
KCCR

Clinical trial experience from KCCR/KNUST

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY, AND KUMASI CENTRE FOR COLLABORATIVE RESEARCH IN TROPICAL MEDICINE

By
Alex Debrah.

KCCR Research areas

- **Malaria**

RTS'S Vaccine Trial

Genetics of host resistance and susceptibility to severe malaria

Improvement in treatment of severe malaria

- **Tuberculosis**

Genetics of host resistance and susceptibility to tuberculosis

- **Entomology**

Insect vectors and parasite transmission in malaria, onchocerciasis and elephantiasis

- **Aflatoxin toxicity**

Aflatoxin ingestion and health impact in a high ingesion area of Ghana

- **Filariasis**

Anti-symbiotic chemotherapy for elimination of Wolbachia in elephantiasis and onchocerciasis

- **Buruli Ulcer**

Multi disciplinary research for improvement of control in Africa.

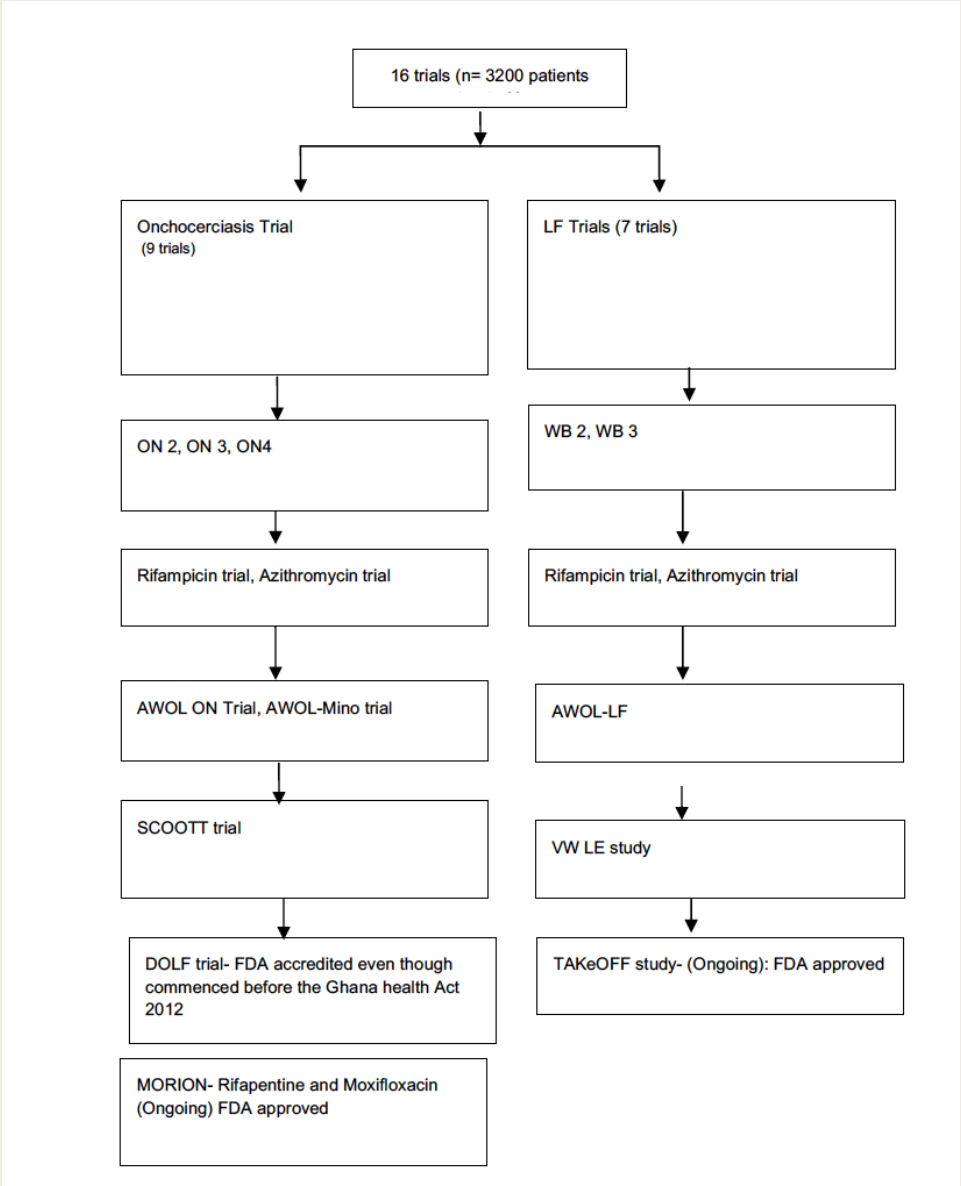
- **Neglected diseases in African Children**

Respiratory infections, stool infections and blood related infections

- **Water Quality**

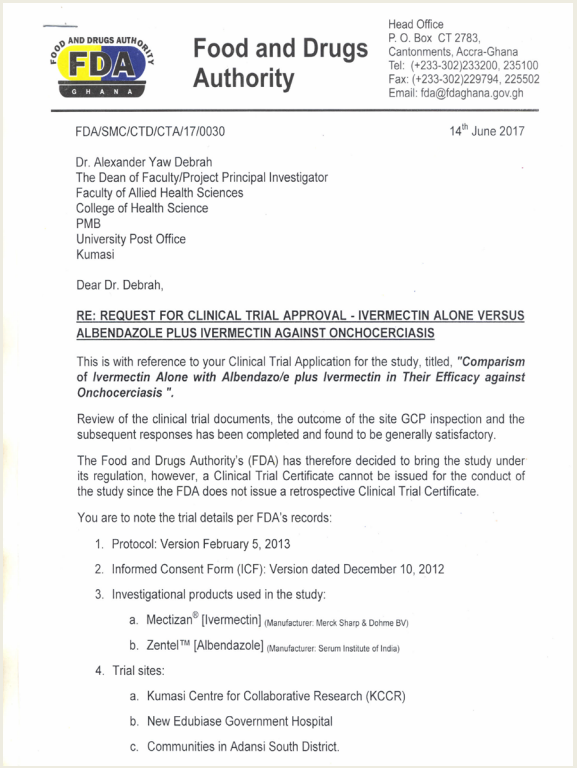
Presence of bacteria in water

Filariasis clinical trials conducted for the past 19 years



Three of the studies were approved by G-FDA-Ghana Public Health Act 2012

DOLF



Food and Drugs Authority

Head Office
P. O. Box CT 2783,
Cantonments, Accra-Ghana
Tel: (+233-302)233200, 235100
Fax: (+233-302)229794, 225502
Email: fda@fdaghana.gov.gh

FDA/SMC/CTD/CTA/17/0030 — 14th June 2017

Dr. Alexander Yaw Debrah
The Dean of Faculty/Project Principal Investigator
Faculty of Allied Health Sciences
College of Health Science
PMB
University Post Office
Kumasi

Dear Dr. Debrah,

RE: REQUEST FOR CLINICAL TRIAL APPROVAL - IVERMECTIN ALONE VERSUS ALBENDAZOLE PLUS IVERMECTIN AGAINST ONCHOCERCIASIS

This is with reference to your Clinical Trial Application for the study, titled, ***"Comparism of Ivermectin Alone with Albendazo/e plus Ivermectin in Their Efficacy against Onchocerciasis ".***

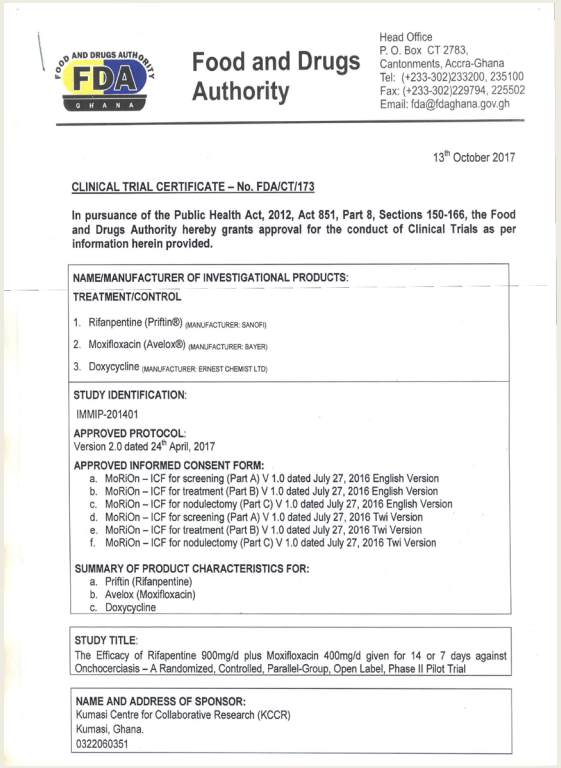
Review of the clinical trial documents, the outcome of the site GCP inspection and the subsequent responses has been completed and found to be generally satisfactory.

The Food and Drugs Authority's (FDA) has therefore decided to bring the study under its regulation, however, a Clinical Trial Certificate cannot be issued for the conduct of the study since the FDA does not issue a retrospective Clinical Trial Certificate.

You are to note the trial details per FDA's records:

1. Protocol: Version February 5, 2013
2. Informed Consent Form (ICF): Version dated December 10, 2012
3. Investigational products used in the study:
   a. Mectizan® [Ivermectin] (Manufacturer: Merck Sharp & Dohme BV)
   b. Zentel™ [Albendazole] (Manufacturer: Serum Institute of India)
4. Trial sites:
   a. Kumasi Centre for Collaborative Research (KCCR)
   b. New Edubiase Government Hospital
   c. Communities in Adansi South District.

MORION



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13th October 2017

CLINICAL TRIAL CERTIFICATE – No. FDA/CT/173

In pursuance of the Public Health Act, 2012, Act 851, Part 8, Sections 150-166, the Food and Drugs Authority hereby grants approval for the conduct of Clinical Trials as per information herein provided.

NAME/MANUFACTURER OF INVESTIGATIONAL PRODUCTS:

TREATMENT/CONTROL

1. Rifanpentine (Priftin®) (MANUFACTURER: SANOFI)
2. Moxifloxacin (Avelox®) (MANUFACTURER: BAYER)
3. Doxycycline (MANUFACTURER: ERNEST CHEMIST LTD)

STUDY IDENTIFICATION:
IMMIP-201401

APPROVED PROTOCOL:
Version 2.0 dated 24th April, 2017

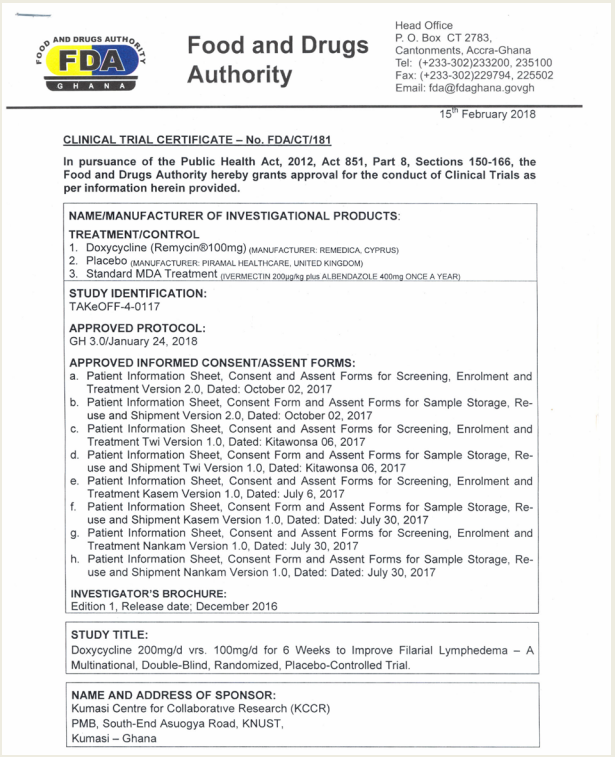
APPROVED INFORMED CONSENT FORM:
a. MoRiOn – ICF for screening (Part A) V 1.0 dated July 27, 2016 English Version
b. MoRiOn – ICF for treatment (Part B) V 1.0 dated July 27, 2016 English Version
c. MoRiOn – ICF for nodulectomy (Part C) V 1.0 dated July 27, 2016 English Version
d. MoRiOn – ICF for screening (Part A) V 1.0 dated July 27, 2016 Twi Version
e. MoRiOn – ICF for treatment (Part B) V 1.0 dated July 27, 2016 Twi Version
f. MoRiOn – ICF for nodulectomy (Part C) V 1.0 dated July 27, 2016 Twi Version

SUMMARY OF PRODUCT CHARACTERISTICS FOR:
a. Priftin (Rifanpentine)
b. Avelox (Moxifloxacin)
c. Doxycycline

STUDY TITLE:
The Efficacy of Rifapentine 900mg/d plus Moxifloxacin 400mg/d given for 14 or 7 days against Onchocerciasis – A Randomized, Controlled, Parallel-Group, Open Label, Phase II Pilot Trial

NAME AND ADDRESS OF SPONSOR:
Kumasi Centre for Collaborative Research (KCCR)
Kumasi, Ghana.
0322060351

LEDoxy



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15th February 2018

CLINICAL TRIAL CERTIFICATE – No. FDA/CT/181

In pursuance of the Public Health Act, 2012, Act 851, Part 8, Sections 150-166, the Food and Drugs Authority hereby grants approval for the conduct of Clinical Trials as per information herein provided.

NAME/MANUFACTURER OF INVESTIGATIONAL PRODUCTS:

TREATMENT/CONTROL
1. Doxycycline (Remycin®100mg) (MANUFACTURER: REMEDICA, CYPRUS)
2. Placebo (MANUFACTURER: PIRAMAL HEALTHCARE, UNITED KINGDOM)
3. Standard MDA Treatment (IVERMECTIN 200µg/kg plus ALBENDAZOLE 400mg ONCE A YEAR)

STUDY IDENTIFICATION:
TAKeOFF-4-0117

APPROVED PROTOCOL:
GH 3.0/January 24, 2018

APPROVED INFORMED CONSENT/ASSENT FORMS:
a. Patient Information Sheet, Consent and Assent Forms for Screening, Enrolment and Treatment Version 2.0, Dated: October 02, 2017
b. Patient Information Sheet, Consent Form and Assent Forms for Sample Storage, Re-use and Shipment Version 2.0, Dated: October 02, 2017
c. Patient Information Sheet, Consent and Assent Forms for Screening, Enrolment and Treatment Twi Version 1.0, Dated: Kitawonsa 06, 2017
d. Patient Information Sheet, Consent Form and Assent Forms for Sample Storage, Re-use and Shipment Twi Version 1.0, Dated: Kitawonsa 06, 2017
e. Patient Information Sheet, Consent and Assent Forms for Screening, Enrolment and Treatment Kasem Version 1.0, Dated: July 6, 2017
f. Patient Information Sheet, Consent Form and Assent Forms for Sample Storage, Re-use and Shipment Kasem Version 1.0, Dated: Dated: July 30, 2017
g. Patient Information Sheet, Consent and Assent Forms for Screening, Enrolment and Treatment Nankam Version 1.0, Dated: July 30, 2017
h. Patient Information Sheet, Consent Form and Assent Forms for Sample Storage, Re-use and Shipment Nankam Version 1.0, Dated: Dated: July 30, 2017

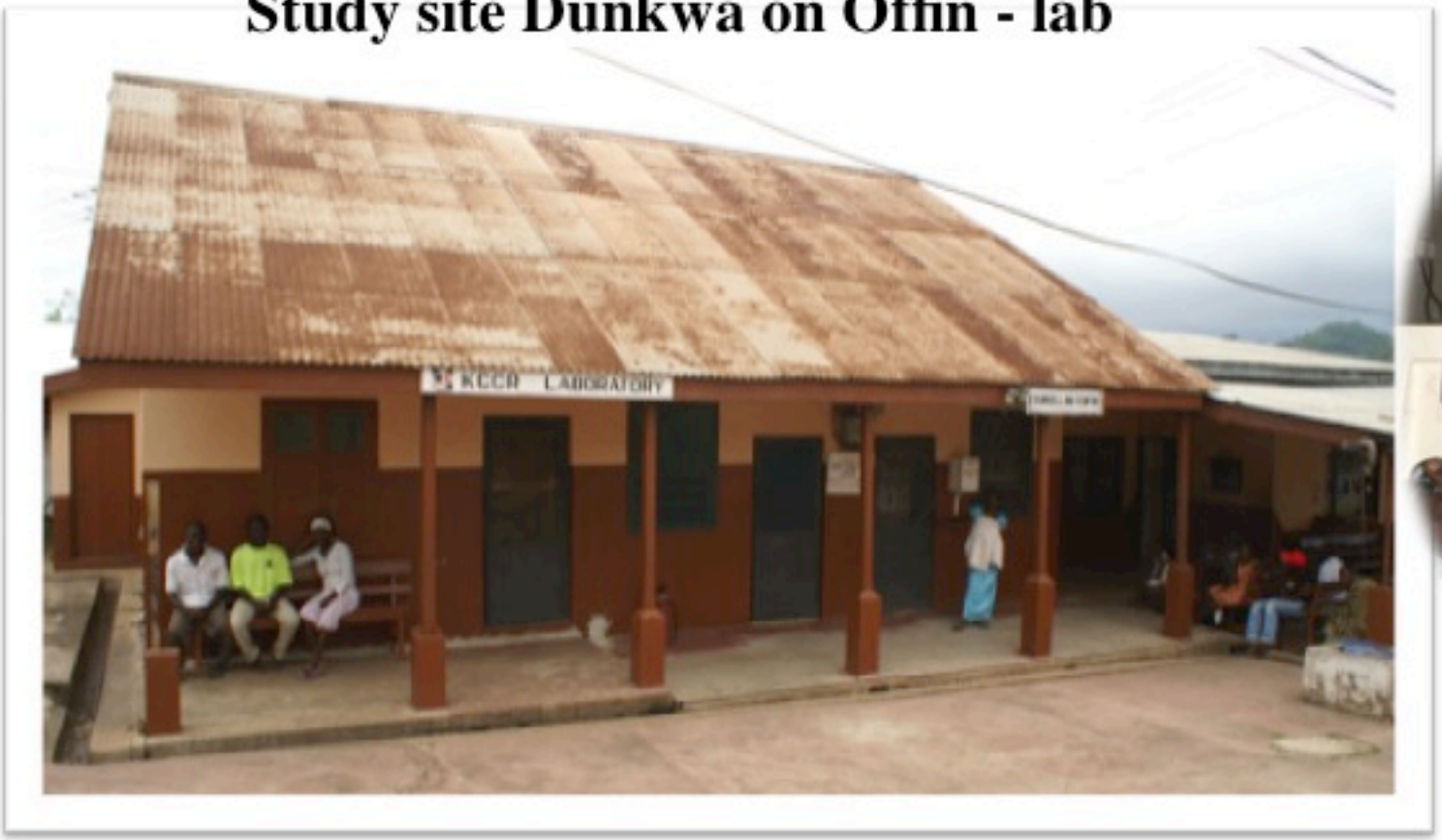
INVESTIGATOR'S BROCHURE:
Edition 1, Release date; December 2016

STUDY TITLE:
Doxycycline 200mg/d vrs. 100mg/d for 6 Weeks to Improve Filarial Lymphedema – A Multinational, Double-Blind, Randomized, Placebo-Controlled Trial.

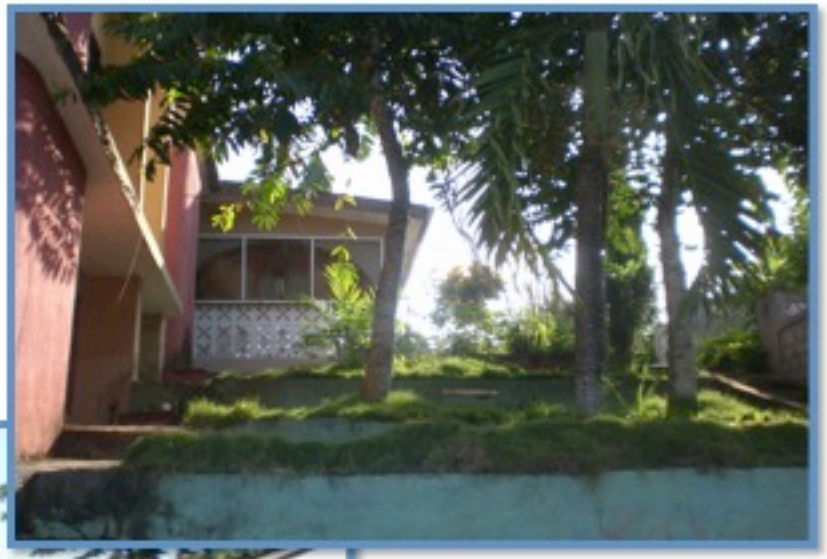
NAME AND ADDRESS OF SPONSOR:
Kumasi Centre for Collaborative Research (KCCR)
PMB, South-End Asuogya Road, KNUST,
Kumasi – Ghana

KCCR research sites

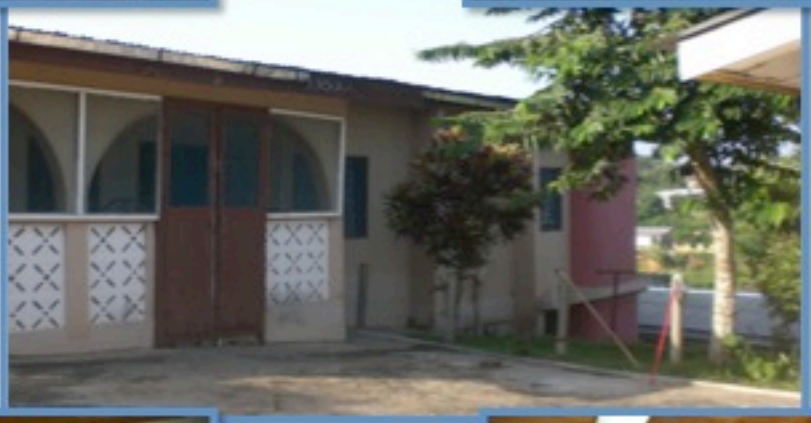
Study site Dunkwa on Offin - lab



Eqipped with e.g. : - running water/electricity + generator as back-up
- microscopes
- biosafety hood
- fridges
- liquid nitrogen tank
- hot air sterilizer

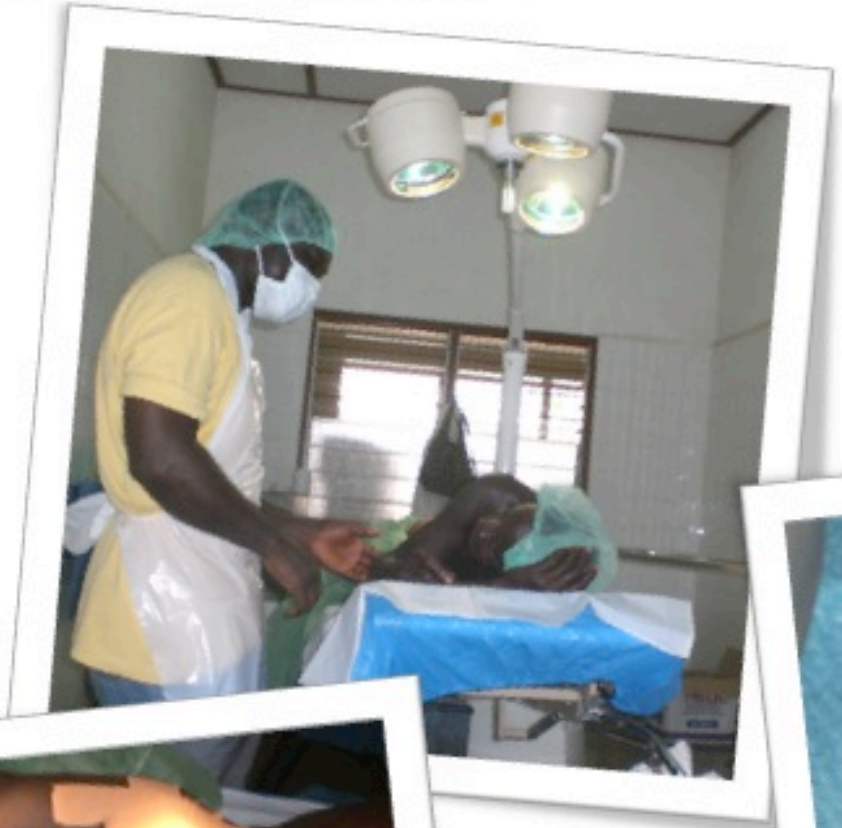


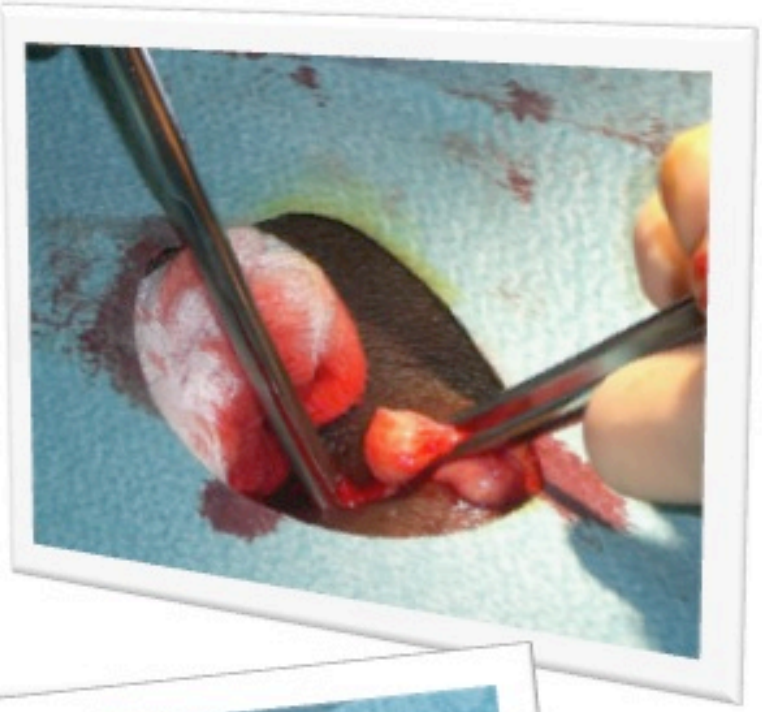
Accomodation facilities:
-12 bed rooms
- Office
- store rooms
- watchmen/security area
- parking lot

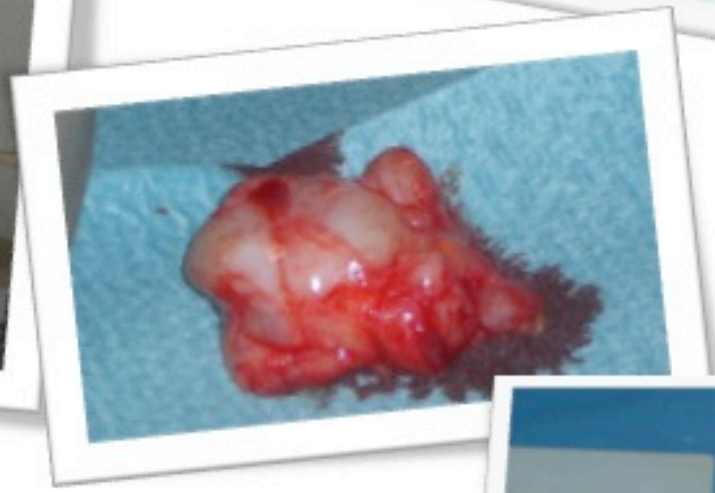


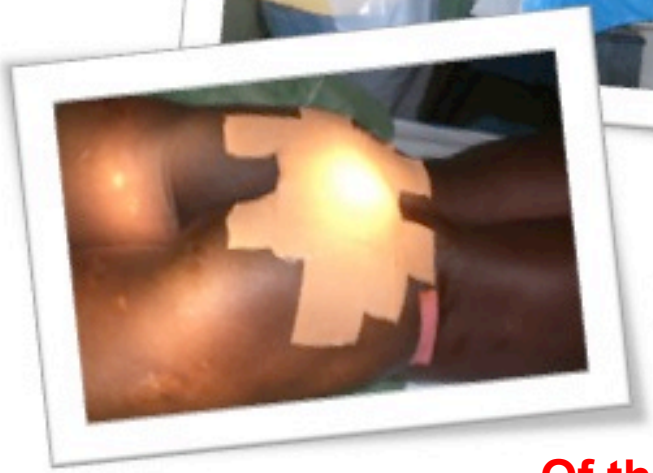
Our Compliance is always high

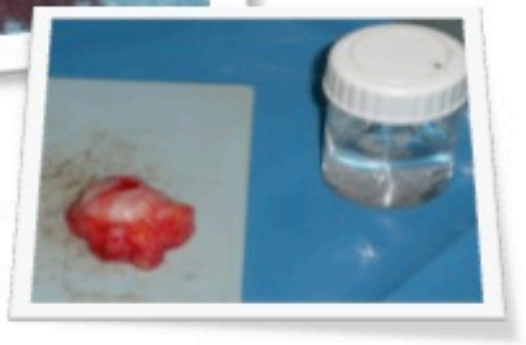
Operating theater:
-Air conditioned
- sterile working conditions
- ward with 12 beds available











Nodulectomies in local anaesthesia

Of the 233 patients, only 5 minor infection

The Kumasi team has rich experience in conducting clinical trials

The TAKeOFF Platform

- With 2012 London declaration on NTDs, it is expected that more clinical trials will take place in Africa

- What is lacking however, is expertise to conduct CT in GCP manner

- In 2017, the German Federal Ministry of Education and Research (BMBF) granted the TAKeOFF consortium over 8 million Euros to build a CT platform for filariasis and podocionosis

Bundesministerium
für Bildung
und Forschung

Tackling the Obstacles to Fight Filariasis and Podoconiosis

Research Networks for Health Innovations in Sub-Sahara Africa

The vision:
To make Africa and the world free of Lymphatic Filariasis and Podoconiosis

The mission:
To offer evidence-based treatment, control and elimination of lymphatic filariasis and podoconiosis in Africa through networking, awareness programs and empowering researchers and local health authorities within the African region.

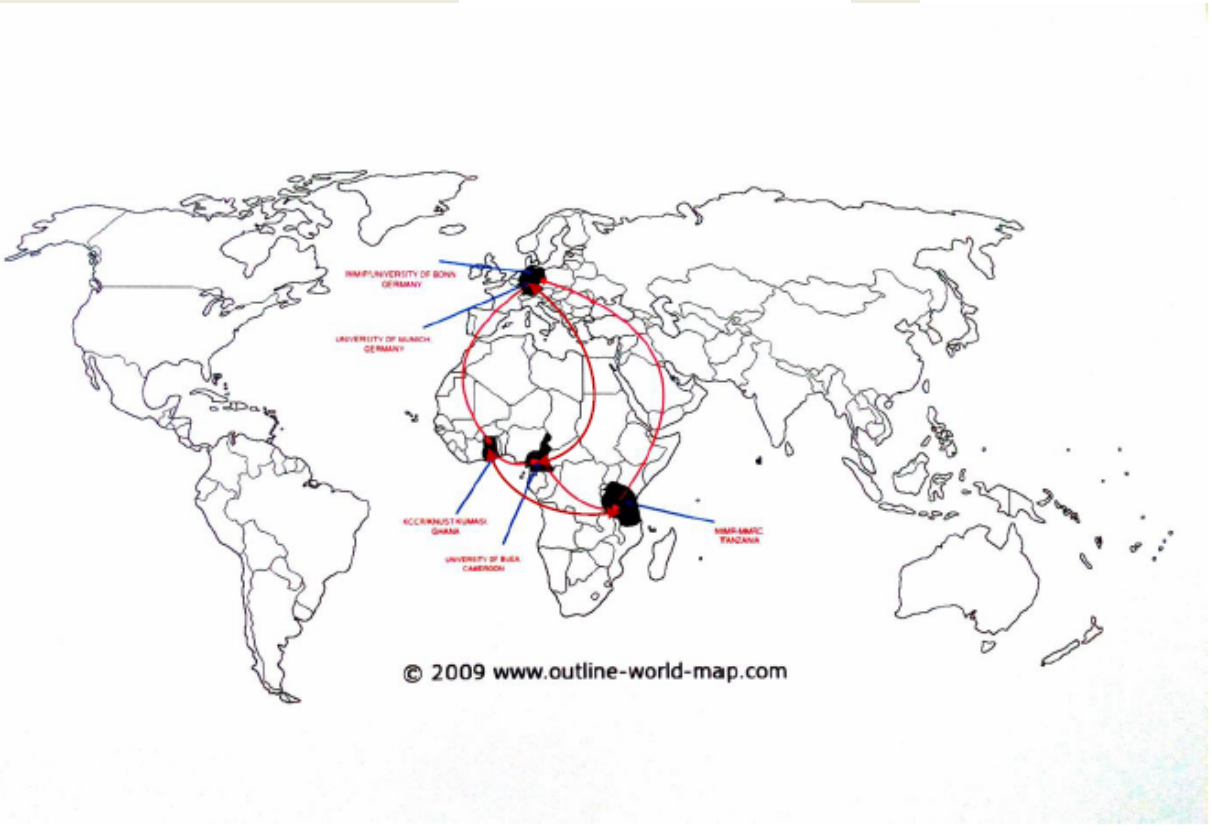
TAKeOFF Consortium partners

KWAME NKRUMAH UNIVERSITY OF SCIENCE AND TECHNOLOGY

KCCR

UNIVERSITÄT BONN

LMU LUDWIG-MAXIMILIANS-UNIVERSITÄT MÜNCHEN



UNIVERSITY OF BUEA
UNIVERSITE DE BUEA
KNOWLEDGE WITH WISDOM

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

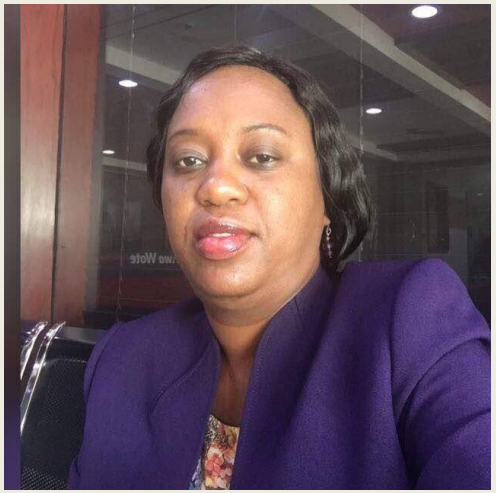
Institutional PIs

Achim Hoerauf

Samuel Wanji

Inge Kroidl

Alex Debrah



Upendo Mwingira

Objectives of the consortium

1

To Establish a multinational Filariasis Clinical Trial Platform (F-Cure) to harmonize procedures to address the specific needs for filariasis control across Africa

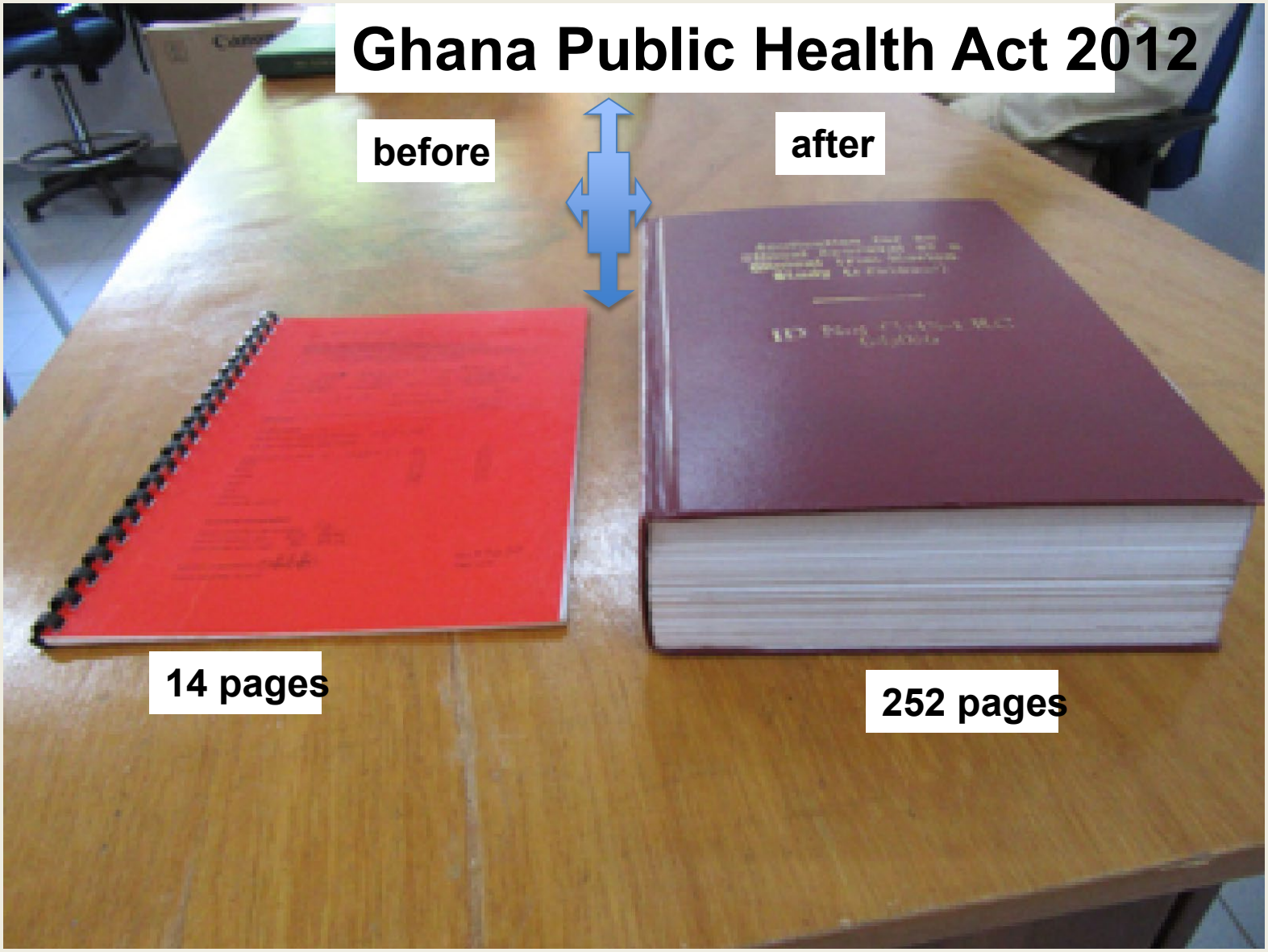
2

To create awareness about the diseases

Status and tasks accomplished

Harmonization of clinical trial procedures

- Consortium met in Kumasi, Ghana in May 2017 to discuss and harmonize the procedures
- 72 SOPs for oncho and LF research have been developed
- GCP Training in Ghana by G-FDA for Ghanaians and Cameroonians
- 252 paged protocol in accordance with GCP have been developed and submitted to
  - Local IRB
  - Ministries of Health
  - Local FDAs


Ghana Public Health Act 2012
before
after
14 pages
252 pages

Human Capacity development goals achieved

- The F-CuRE platform has provided clinical trial performance related courses such as GCP/GLP, internal monitoring, data management and statistics
  - Trial clinicians
  - Trial pharmacists
  - Lab technologists
  - Research assistants
  - Nurses

GCP certificates awarded by G-FDA


FOOD AND DRUGS BOARD
FDB
GHANA

NOGUCHI MEMORIAL INSTITUTE FOR MEDICAL RESEARCH

Certificate of Participation

This is to certify that

Dr. Alex Debrah

has successfully participated in the Good Clinical Practice Workshop organized by Food and Drugs Board From: August 18-22, 2008

Chief Executive
FOOD AND DRUGS BOARD

Workshop Coordinator
Prof. David Ofori-Adjei


FOOD AND DRUGS AUTHORITY

FOOD AND DRUGS AUTHORITY
FDA
GHANA

Certificate of Participation

This is to certify that

DR. ALEXANDER YAW DEBRAH

has successfully participated in the Good Clinical Practice Workshop Organized by the Food & Drugs Authority from June 25-27, 2013

Chief Executive
Food and Drugs Authority
Dr. Stephen K. Opuni

Workshop Coordinator


c d m Training Solutions
professional training
for Africa

Certificate of Training

Good Laboratory Practices Workshop

13th – 14th June 2011
Busua Beach Resort – Takoradi, Ghana

This is to certify that

Dr. Alexander Yaw Debra

Successfully completed the above course covering:
Introduction to GLP; Safety Plan & Manual; Importance of Method Validation & Identifying the components of Quality Assurance; Importance of Quality Control; Basic Statistics; Preparation of a Quality Manual

Director: T Perumal

Facilitator: Dr J F Dames

14th June 2011

saaci
INDIVIDUAL MEMBER

Member of:
South African Quality Institute

c d m Training Solutions
professional training for Africa
Reg No. 2006/056389/23
PO Box 795 Bergbron 1712; Tel: +2711 673 9726 Fax: +2711 673 1028 Website: www.cdmtsol.co.za


FOOD AND DRUGS AUTHORITY

FOOD AND DRUGS AUTHORITY
FDA
GHANA

Certificate of Participation

This is to certify that

ALEX DEBRAH

has successfully participated in the Good Clinical Practice Workshop Organized by the Food & Drugs Authority from 14th – 16th August 2018

Chief Executive Officer
Delese A. A. Darko (Mrs)

Workshop Coordinator
Seth Seaneke (Mr)

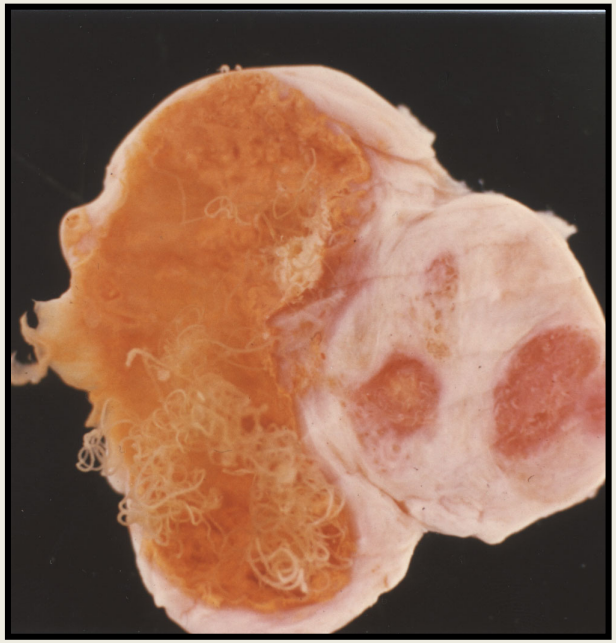
Infrastructural Capacity development goal achieved

- **Infrastructural dev't**
  - Field laboratories are in place
  - 4 minus 80 freezers
  - Lab equipment, etc.
  - Drug storage facility with temp control system
  - Fire proof cabinets for document storage
  - Fleet of cross country vehicles for field work
  - Archived room for document storage
  - Liquid nitrogen tanks
  - Microscopes
  - Etc.

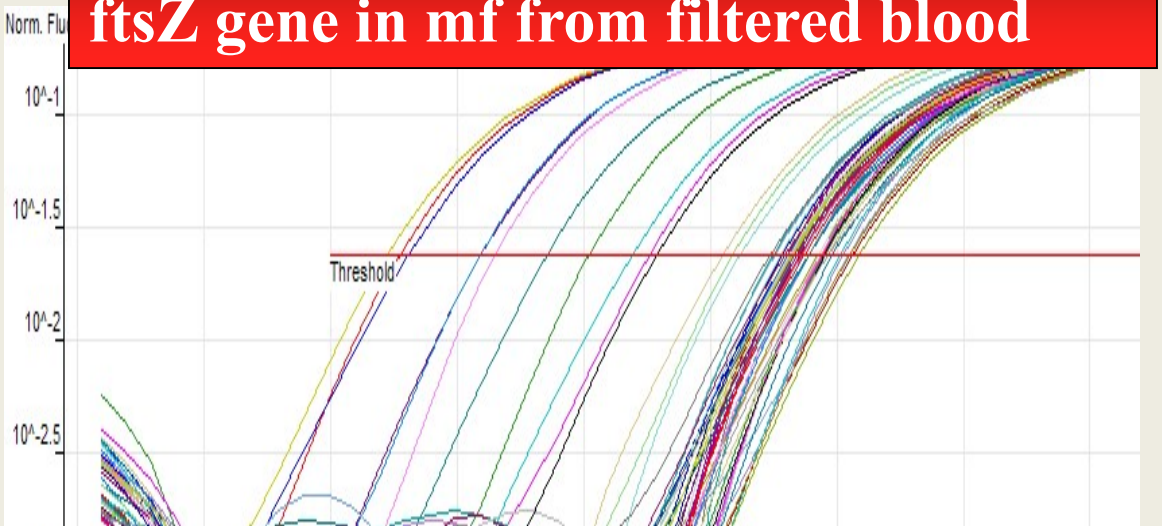
Molecular Biology lab - PCR machines

Safety hood for PCR mastermix

Cobert Machine



Real time PCR to detect *Wolbachia* ftsZ gene in mf from filtered blood




13/3/2008 10:24


Bench for DNA extraction.
Keep clean after use
DANGER

Filariasis team has cross country vehicles for field work

Summary and Conclusion

- The TAKeOFF consortium is building a strong F-Cure platform for the conduct of Phase 2-4 clinical trials.

Thank you

BMBF Research Networks for Health Innovations in Sub-Saharan Africa, Kick-Off Meeting, Tanzania 2017

photo: Pavel Desort