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Nabila and David (LSHTM, Gaborone)

Philippa (LSHTM, London)

Timothée (Institut Pasteur, Paris)

Greetings from Gaborone!

We continue to make progress with ethical and regulatory submissions, and look forward to commencing patient recruitment as soon as possible.

We are also busy planning the Health Economics Training Course for late November, which will take place in Blantyre.

Philippa is in contact with financial / administrative colleagues at our African partner sites to plan visits for October-November. Thank you to those who have already provided their availability.

In this issue we introduce colleagues from our two partners in Malawi—welcome to all! Further colleagues at both sites will be recruited shortly.



Ethical and regulatory updates

All sites have started the process of ethical and regulatory approvals. Here is a reminder of how the process works:



Below is a summary of submissions undertaken to date:

Institutional review	Ethical Approval	Regulatory Approval
<p>Submitted to:</p> <ul style="list-style-type: none"> University of Cape Town, South Africa Institute of Infectious Diseases, Uganda Kamuzu Central Hospital, Malawi Queen Elizabeth Hospital, Malawi Princess Marina Hospital, Botswana University of Zimbabwe <p>Approval/Letter of Support received from:</p> <ul style="list-style-type: none"> University of Cape Town Institute of Infectious Diseases, Uganda Kamuzu Central Hospital, Malawi Queen Elizabeth Hospital, Malawi <p>Decision pending from:</p> <ul style="list-style-type: none"> University of Botswana Princess Marina Hospital, Botswana University of Zimbabwe 	<p>Submitted to:</p> <ul style="list-style-type: none"> University of Botswana on 23/06 University of Cape Town, South Africa Human Research Ethics Committee on 04/09 National Health Sciences Research Committee, Malawi, on 07/09 <p>The team is currently preparing the application forms for submissions in Uganda and Zimbabwe.</p>	<p>Submitted to:</p> <ul style="list-style-type: none"> Drug Regulatory Unit, Botswana on 26/06 <p>The team is currently preparing the application forms for submissions in all other countries.</p>

Training Courses

We are excited to run the AMBITION Health Economics Training Course in Blantyre from Monday 20th to Friday 24th November. Preparations are underway and we will shortly be in touch with all attendees to organize flights and accommodation. The course will be led by Professor Louis Niessen (Liverpool School of Tropical Medicine), supported by two of his PhD students. It is hoped that Nabila and David will also be in attendance. Thank you to those who nominated attendees for the course. We look forward to meeting you soon!

We hope to run the Mycology Course at the University of Cape Town in 2018. More information will be provided in due course.



PhD Opportunity at Institut Pasteur

Four applications for this opportunity were received, which are currently being reviewed by the team at Institut Pasteur. We look forward to welcoming the successful candidate to the AMBITION team in late October / early November.



MSc Scholarship at LSHTM

Dr. Tshepo Leeme, from the Botswana Harvard Partnership, arrives in London on 21 September to begin her scholarship in MSc Epidemiology. We look forward to welcoming her to LSHTM.



Malawi-Liverpool Wellcome Trust Clinical Research Programme (MLW)

The Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW), in partnership with the University of Malawi College of Medicine (COM), the Malawi Ministry of Health and Queen Elizabeth Central Hospital (QECH) conducts internationally competitive, cutting-edge, fundamental clinical and epidemiological research that addresses the health challenges facing populations of sub-Saharan Africa and beyond. The Wellcome Trust Research Laboratories are situated on the grounds of QECH, close to the CoM main campus. Queen Elizabeth Central Hospital (QECH) is one of Malawi's four national referral hospitals, is the main teaching base for the CoM, and functions as the district general hospital for a local population of ~1 million. This institutional partnership will host the AMBITION trial in Blantyre.



Malawi-Liverpool-Wellcome Trust Clinical Research Programme



**Queen Elizabeth Central Hospital
(Malawi Ministry of Health)**



University of Malawi College of Medicine (COM)

Dr. Henry Mwandumba (Study Doctor and Local PI)

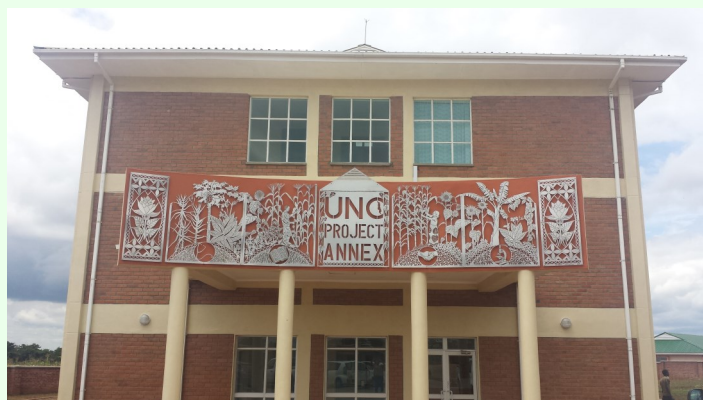
I am a Clinician Scientist and Head of the Mucosal Immunology Group at the Malawi-Liverpool-Wellcome Trust Clinical Research Programme, University of Malawi College of Medicine, and Consultant Physician at Queen Elizabeth Central Hospital. I obtained my medical degree from the University of Zimbabwe School of Medicine and specialised in General (Internal) Medicine and Infectious Diseases in Liverpool, UK. My research focuses on understanding the effects of HIV on pulmonary immunity and predisposition to respiratory infections, especially tuberculosis. I am President of the Immunology Society of Malawi (ISM), President-elect of the Federation of African Immunological Societies (FAIS) and Treasurer of the East, Central and Southern Africa College of Physicians (ECSACoP). My research is supported by funding from the Wellcome Trust, BMGF, NIH and the MRC through the MRC/DfID African Research Leader Award. I am AMBITION's PI in Blantyre and look forward to working with a fantastic team that we have on site, colleagues from other sites and institutions, as well as the entire AMBITION Trial team.



More colleagues will be recruited to the AMBITION team in Blantyre very soon!

UNC Project Malawi (Lilongwe Medical Relief Fund Trust)

The UNC Project is a collaboration between the University of North Carolina and the Malawi Ministry of Health. Established in 1999 with a focus primarily on sexually transmitted infections and HIV, the project's research focus has expanded to encompass HIV treatment of adults and children, treatment of HIV opportunistic infections, biologic HIV prevention including vaccines, maternal child health and family planning, HIV associated malignancies, and implementation science.



Here are some of the key members of the AMBITION team, who are introduced on the next pages. From left to right:

Felix Namalueso (Data Manager), Chimwemwe Chawinga (Co-ordinator), Wilberforce Mhango (Pharmacist), Cecilia Kanyama (PI), Mina Hosseinipour (Investigator), Emily Kumwenda (Lead Nurse), Creto Kanyemba (Microbiology Supervisor)

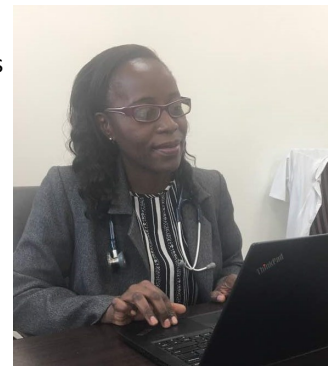
Professor Mina Hosseinipour, MD, MPH (Investigator)

I am Professor of Medicine at the UNC-CH School of Medicine and the scientific director at UNC Project in Lilongwe. I am an internal medicine and infectious diseases physician with research interests in the treatment of HIV and its complications, including opportunistic infections such as TB and cryptococcal meningitis. In my role as investigator for the AMBITION trial, I will support research operations at the Lilongwe site and play an active role in the mentorship of junior investigators.



Dr. Cecilia Kanyama, MBBS, FCP(SA) (Lilongwe PI)

I am an internal medicine physician with a special interest in the improvement of diagnostic tests for HIV and associated conditions. I am a principal investigator for TB, Cryptococcal Meningitis and HIV treatment trials at UNC Project, where we work in collaboration with Kamuzu Central Hospital (KCH) in Lilongwe. I have a particular interest in the management of cryptococcal disease in resource-limited settings. Having been the principal investigator in previous cryptococcal meningitis clinical trials, I bring both clinical and research expertise in this field, and hence I will lead the clinical and operational aspects of the AMBITION trial in Lilongwe.



Chimwemwe Chawinga (Study Co-ordinator / Junior Investigator)

I hold a Diploma in Clinical Medicine and a Bachelors in Health Systems Management. I have seven years of experience as an investigator in clinical trials, and am an accomplished clinician in the management of HIV and related illnesses. From 2014 to 2017 I have been a Clinician and an investigator in the ACTA Trial, just completed. My research interests are in the treatment of HIV/AIDS and its complications, including opportunistic infections such as cryptococcal meningitis, TB and KS. As an investigator and study coordinator for AMBITION I will play an active role in making sure the study is conducted well according to the protocol, and according to good clinical practices. I will ensure quality clinical management of the trial participants. I will coordinate all activities for laboratory, pharmacy, and clinical areas and data entry.



Emily Kumwenda (Lead Study Nurse)

I work as a Study Nurse, and joined the ACTA Team in July 2013. I am interested in providing care to HIV-positive patients.

As the Lead Nurse for AMBITION my responsibilities will cover patient identification, consenting and enrolment, collection of study samples, ordering of drugs for participants from the pharmacy, administering the drugs as per the protocol, and ordering equipment for study procedures.

I will also communicate with patients to remind them of follow up dates, check on them to enquire how they are faring, and conduct follow up visits with clinicians as scheduled.



Felix Namalueso (Data Manager)

I am Felix Namalueso, and I have been working at UNC Project for the past 9 years. Currently I am working as Data Manager for the ACTA, DREAMM and AMBITION studies. I am responsible for all Data Management issues for the studies, which includes attending to queries from the Data Management Centres (DMC) and from the study protocol team.



Wlberforce Mhango (Pharmacist)

I hold a BA in Logistics and Supply Chain Management, and a DipPharm. I am a registered Pharmacy Technologist under the Pharmacy, Medicines and Poisons Board. I have served the pharmacy profession and contributed significantly to the pharmaceutical services in Malawi since 2006. I joined UNC Project in 2007, following which I was elevated to a post of UNC Pharmacy Co-ordinator in 2008. Currently I am a Pharmacist of Record for Aids Clinical Trials Group (ACTG), and Associate Pharmacist in different studies that are being conducted at UNC Project Malawi. I was the lead Pharmacy personnel for the ACTA Trial, just completed, and will act in the same capacity for the AMBITION study. I will also be the Importer of Records for both the Blantyre and Lilongwe sites.



Creto Kanyemba (Medical Laboratory Technologist)

I received my Certificate and my Diploma in Medical Laboratory Technology from Malawi College Of Health Sciences, Malawi, in 1993 and 1998 respectively.

I Worked as a Medical Laboratory Technician in several government hospitals from 1994 to 2004 (Kamuzu Central Hospital, Salima District Hospital, Ntchisi District Hospital and Bwaila Hospital), following which I joined Malawi Aids Counseling and Resource Organization, where I worked as a Medical Laboratory Technician.

In 2005 I joined UNC Project as a Research Medical Laboratory Technician, then as a Microbiology Supervisor. I have been involved in two cryptococcal studies, including the ACTA trial. I have also acted as a Training Officer and Safety Officer for the UNC Project Laboratory for over four years. I have attended training in the USA, and have co-authored five publications relating to cryptococcal meningitis, gonorrhea and TB.

I will act as a Medical Laboratory Technologist for the AMBITION study, where I will make sure that the study is undertaken correctly according to the protocol so that the results generated from our laboratory should be reliable and credible.

