

Ambition News

THE AMBITION-CM

TRIAL NEWSLETTER

(ISSUE 9: MAY 2018)



AMBITION-CM

AMBIsome Therapy Induction Optimization

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TEAM EMAIL ADDRESS: **AMBITION@LSHTM.AC.UK**

Greetings from Gaborone!

Thank you to colleagues at all sites who have been working tirelessly on submissions these last few months. We have made good progress and are looking forward to opening the 5 remaining sites to recruitment by June/July 2018.

We continue to screen patients in Botswana, and have also started to plan Site Initiation Visits (SIVs) to Harare and Cape Town as well as our two sites in Malawi.









We ran a successful GCP and Clinical Trials Course in Gaborone from 12-16 March 2018. It was a great opportunity for AMBITION colleagues from all sites to come together and share their experiences.

We will be convening at Woburn House in London in a few weeks time (23-24 May) for the 2018 Investigators' Meeting. We are looking forward to having PIs and study doctors in one place to discuss all things AMBITION. See you in a couple of weeks!

Best Wishes,

Joe

Regulatory Submission Updates

Botswana-Harvard Partnership 	Site open to recruitment. 12 patients have been randomised to date. The study team continue to do a great job and to actively screen potential patients at Princess Marina Hospital.
University of Cape Town 	Medicines Control Council (MCC) approval was issued on 23 March 2018; we now await the MCC approval of Protocol Version 2.1. We hope to open the Cape Town site to recruitment in June 2018.
University of Zimbabwe 	We await approval from the Research Council of Zimbabwe (RCZ) . We hope to open the Zimbabwe site to recruitment in June 2018.
UNC Project Malawi 	Comments from the Pharmacy, Medicines and Poisons Board (PMPB) were received in late April, to which we are currently responding. We hope to open the two Malawi sites to recruitment in July 2018.
Malawi-Liverpool Wellcome Trust Clinical Research Programme 	
IDI Uganda 	Submission to the Ugandan National Drug Authority (NDA) was made in April 2018, and we await their response. We hope to open the Uganda site to recruitment in July 2018.



European & Developing Countries
Clinical Trials Partnership





GCP and Clinical Trials Courses in Gaborone, 12-16 March 2018

From 12– 16 March 2018, AMBITION colleagues gathered in Gaborone to take part in a 3-day Clinical Trials Course, followed by a 2-day Good Clinical Practice (GCP) Course.

Three participants from each AMBITION recruiting site were in attendance, plus a contingent from BHP, and other local delegates. Presentations were given by a range of colleagues including Profs. Joe Jarvis and Tom Harrison, Drs. David Lawrence and Nabila Youssouf, and Patricia Henley (Head of LSHTM's Research Governance & Integrity Office). The delegates also enjoyed a range of collaborative group sessions.

We packed a good deal into the courses: the delegates had the opportunity to learn about:

- **Principles of Trials, Randomisation, Protocol Critique, Electronic Data Capture, SAE Reporting, and trial management and monitoring**
- **Principles of GCP, Ethics, Regulatory Authorities, Informed Consent, IMPs and Safety evaluation**



AMBITION colleagues were able to network and share experiences, which was particularly valuable as we prepare for the onset of patient recruitment. The team also enjoyed a meal at one of Gaborone's best restaurants!

We would like to thank all the presenters, and the many administrative staff at BHP for their logistical support and guidance.

We looking forward to the next AMBITION course (Medical Mycology) to be held in Cape Town from 10-14 December 2018.





BHP Trial Audit

In late March 2018, the AMBITION team at the Botswana-Harvard Partnership (BHP) welcomed Patricia Henley, Head of LSHTM's Research Governance and Integrity Office, to Gaborone to conduct the first formal regulatory audit of the AMBITION study. We are delighted to report that Patricia provided zero findings as a result of the audit: a result which she has encountered only a handful of times during her career! This gives the BHP and LSHTM teams confidence in their processes and procedures, and we feel reassured that we are managing our recruitment according to sound GCP standards. Many thanks to Patricia and to all those at BHP and LSHTM who worked hard to prepare for the audit.

Investigators' Meeting

We are very much looking forward to welcoming everyone to London for the Investigators' Meeting from 23-24 May 2018 (with most arrivals on 22 May). The meeting will be taking place at **Woburn House Conference Centre, Tavistock Square**. It is a large, light space and we have ensured that you will be well catered for. You should have received communication from Philippa last week detailing the logistics of the event, in addition to the proposed agenda.



Accommodation has been booked at **Premier Inn Kings Cross**.

A reminder that we will be covering all subsistence and travel costs for the duration of the meeting. If you have any specific **dietary requests**, please let us know and we will accommodate. We would also like to take this opportunity to kindly reiterate the importance of **retaining your boarding passes** to satisfy the EDCTP auditors – Sophia will collect these from you upon your arrival.

The meeting will include updates from the PIs and study doctors at each of the recruiting sites, a presentation about the recently completed ACTA study, statistical aspects, as well as additional updates on the lab-based sub-studies, Health Economics, AMNET, and financial project management.

The TSC (Trial Steering Committee) and DMC (Data Monitoring Committee) will be meeting on the afternoon of Wednesday 23rd May, with those members who are not part of the Investigators' Meeting dialling in.

There will also be a short presentation on the new European General Data Protection Regulation (GDPR), which will take effect on 25 May 2018.

Our new EDCTP Project Officer, Johanna Roth, will also be in attendance and will be giving a short presentation on all things EDCTP-related.

If you have any questions or queries, please do not hesitate to contact either Philippa or Sophia at ambition@lshtm.ac.uk.

We look forward to seeing you soon!



We are happy to report that a number of new members have joined us since our last Newsletter. We are pleased to introduce them below:

University of Cape Town

Siphokazi Hlungulu: Research Nurse

I hold a Diploma in Nursing, and am a dedicated Research Nurse on the AMBITION study. From 2009 – 2016 I worked for the City of Cape Town as an Enrolment Nurse, where I assisted with all aspects of enrolment of TB patients receiving anti-retroviral treatment. In 2016 I began working at TB/HIV Association on programmes focussing on Medical Male Circumcision. I then worked on two studies with Dr. Sean Wessarman: A Safety Pharmacokinetic and Resistance to Bedaquiline in XDR TB and HIV (observational study) and Safety Pharmacokinetic and Resistance to Bedaquiline in XDR TB and HIV (an intensive PK sampling sub-study).



Mkhanyiseli Kenneth 'MK' Mpali: Clinical Research Worker



I began my career as a Clinical Research Worker in 2001, specifically as an HIV/AIDS counsellor, and have worked with numerous organisations and physicians. I first became involved in research in 2004, and have been employed at UCT since 2013, within both the Institute of Infectious Diseases and Molecular Medicine and the new Wellcome Centre of Infectious Diseases Research in Africa (CIDRI-Africa) group. Before joining the AMBITION team, I was involved in the KDH TB study, and the MAIT study. My duties include recruiting participants, taking informed consent, counselling, and assisting the study team with various tasks.

Dr. Debbie Maughan: Sub-Investigator

I completed my undergraduate training at the University of Cape Town in 2005, and my FCP training at Groote Schuur Hospital with the University of Cape Town in 2014. I received the Discovery Foundation Academic Award in 2015 which allowed me to undertake full-time research for one year within the Division of Hepatology at Groote Schuur Hospital in the area of Efavirenz Drug Induced Liver Injury. I began working as a specialist in General Medicine at Mitchell's Plain District Hospital in January 2016, where I am still based. My interests include HIV, infectious diseases and hepatology, and I am passionate about providing excellent care within the public sector in South Africa.



UNC Project

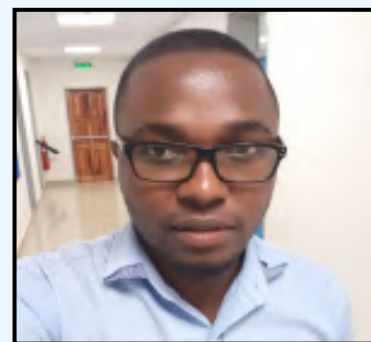
Fanny Mtambo: Administrator



I have been working with the UNC Project since 2005 in the Administration Department, supporting with a wide range of activities. I am responsible for ensuring that technical staff – both local and expatriates – are fully registered with the relevant statutory boards, as well as being responsible for the processing of work permits for expatriates. I provide high level administrative support to the AMBITION and DREAMM studies and teams, co-ordinating all administrative logistics.

Dr. Timothy Kachitosi: Medical Officer

I am heavily involved in AMBITION, in addition to the EDCTP-funded DREAMM study, working as a point of care Doctor. I am currently a Junior Doctor, and dream of undertaking a medical specialty with a focus on epidemiology and infectious diseases. I have a passion for research, so am delighted to be part of the AMBITION team. Prior to joining the UNC Project in 2018, I worked for St John's Hospital as a Medical Doctor.



University of Zimbabwe (UoZ)

Taddy Mwarumba: Study Nurse



I joined UoZ in 2015 as part of the CryptoArt team. I previously worked for the Ministry of Defence for nine years as a senior nursing officer, then as a research nurse with Zimbabwe's Biomedical Research and Training Institute. I hold a BSc Degree in HIV/AIDS Management and Community Development from Chinhoyi University of Technology, a Postgraduate Diploma in Development Studies from the National University of Science and Technology, a Diploma in Community Nursing, a Diploma in Midwifery, a Diploma in Project Planning and Management, a Diploma in nursing, and a Certificate in Systemic Counselling. I have a passion for public health issues, especially HIV/AIDS and opportunistic infections, and I hope to enhance my skills by undertaking a Masters in Public Health in the future. My responsibilities in AMBITION include recruitment of participants, administration of study drugs, informing participants of their laboratory results and advising the study team of any SAEs according to Protocol.



Malawi-Liverpool-Wellcome Trust Clinical Research Programme (MLW)

Dr. Henry Mzinganjira: Study Physician

I obtained a Bachelor of Medicine and Bachelor of Surgery in 2006 from the University of Malawi College of Medicine. I completed my internship programme in 2008, after which I worked as a District Health Officer for two years, where I was responsible for managing all health services in the Mzimba District. I then worked as a Medical Registrar for QECH/College of Medicine and for Groote Schuur Hospital/University of Cape Town, for a following 4 years. Following this, I was employed as a Study Doctor for the START study at MLW, and in 2017 I qualified as an Internal Medicine Specialist after obtaining a Master of Medicine [Internal Medicine] from the University of Malawi College of Medicine. I am currently the Head of the Renal unit at QECH. My professional research interests are focussed upon non-communicable diseases, in particular diabetes and hypertension in relation to kidney diseases.



Sophia Hafeez: Project Assistant



I joined LSHTM in April 2018. I completed my Undergraduates degree in Biology and proceeded to undertake my Masters' in Global Health and Development at UCL. I previously worked at UN-SPIDER in Bonn, where I was responsible for overseeing the Information Management department, in addition to co-leading their Awareness Raising efforts. I currently work as a Project Assistant at LSHTM, assisting Philippa and the wider team with day-to-day administration, communications and logistical tasks.

Events of Interest

Please visit the links below for further information on these events of interest as well as the processes required to register/attend these sessions:

- [AIDS 2018: Amsterdam, 23-27 July 2018](#)
- [5th International Conference on Neglected Tropical and Infectious Diseases: Boston, MA, 29-30 August 2018](#)
- [HIVR4P: Madrid, 21-25 October 2018](#)
- [20th International Conference on Meningitis and Septicaemia Research, San Francisco, 26-27 November 2018](#)