

AMBITION News

The Ambition-cm Trial Newsletter
(Issue 12: September 2018)



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@ambitioncm2020

Please do encourage
colleagues to 'follow' us!



Nametso Lekwape (Senior Research Nurse at BHP) with
Dr. Tawanda Zinyandu (Study Doctor, UoZ) and Edward
Makaha (Research Nurse, UoZ) at the UoZ SIV

Greetings from Gaborone!



Many thanks to colleagues at all sites who continue to work tirelessly on AMBITION. We have made excellent progress during the busy month of August.

Since our last Newsletter, we **have opened for recruitment** in both **Uganda (Kampala and Mbarara)** and **Malawi (Lilongwe and Blantyre)**. SIVs at all four sites took place in August and we are grateful to colleagues for their hospitality and hard work.

We congratulate **Dr. Kenneth Ssebambulidde** from IDI Uganda, who has been accepted onto the **MSc in Immunology of Infectious Diseases** at the London School of Hygiene and Tropical Medicine (LSHTM). We look forward to welcoming him in chilly London in a few weeks' time!

We are also happy to share profiles of some more AMBITION colleagues from **Harare, Kampala and Mbarara**.

The second **AMNET Skype Meeting** of 2018 took place on **22 August**. Several new members were welcomed and the meeting provided a great platform for discussions on everything from situational analysis to website development.

The **EDCTP** have recently released **3 relevant grant calls**—more details on Page 8.

We are happy to have recruited **27 patients** as of 6 September. We look forward to enrolling the first patients in Uganda and Malawi very soon!

Best Wishes,

Joe





Recruitment Update (as of 6 September 2018)

**Botswana-Harvard Partnership
(Gaborone)**



17

The last patient was recruited on **2 August 2018**

**University of Cape Town
(Cape Town)**



04

The last patient was recruited on **3 September 2018**

**University of Zimbabwe
(Harare)**



06

The last patient was recruited on **3 September 2018**

**UNC Project Malawi
(Lilongwe)**



We look forward to enrolling the first patient very soon!

**Malawi-Liverpool Wellcome Trust
Clinical Research Programme
(Blantyre)**



We look forward to enrolling the first patient very soon!

**IDI Uganda –Kampala
IDI Uganda –Mbarara**



We look forward to enrolling the first patient very soon!

Second MSc Student



As we approach the new UK academic year, we would like to congratulate **Dr. Kenneth Ssebambulidde**, who has been accepted onto the **MSc in Immunology of Infectious Diseases** at the LSHTM. Kenneth joins us from IDI Uganda where he has been working as a Study Doctor.

We are very much looking forward to welcoming Kenneth to London in a few weeks time—just in time for the autumnal UK weather! We wish him safe travels!





Uganda SIV



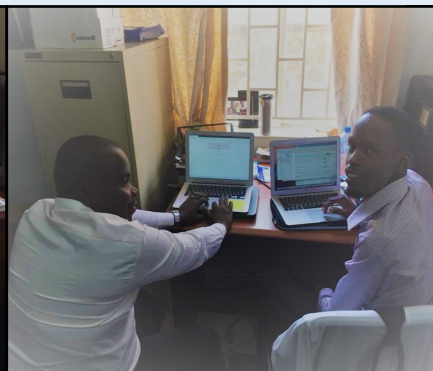
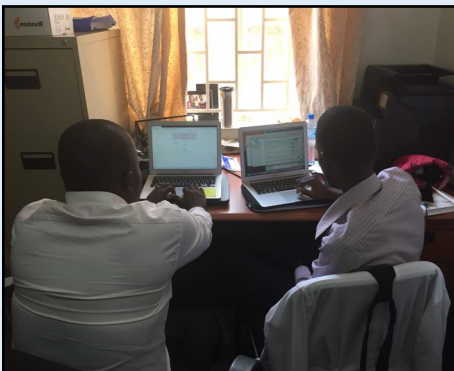
The Uganda SIV took place from **6-8 August 2018** at the **Infectious Diseases Institute (IDI), Kampala**. Prof. Joe Jarvis, Dr. Nabila Youssouf and Dr. David Lawrence from LSHTM and Prof. Tom Harrison from SGUL were warmly welcomed by our Kampala team.

Dr. David Lawrence also spent some time with our team at the **Mbarara Regional Referral Hospital**, where comprehensive training on the Electronic Data Capture tool (EDC) was undertaken by Study Doctors and Nurses.

The SIV was a resounding success, with important discussions on screening, clinical procedures and the study protocol. It was also a great opportunity for our IDI Kampala team to get in some Health Economics practice on the EDC!

We would like to thank our colleagues in both Kampala and Mbarara for their generous hospitality and for their hard work these past few months.

We are excited to enrol our first patient and are optimistic that our recruitment numbers will reflect our colleagues' efforts.



Malawi SIV



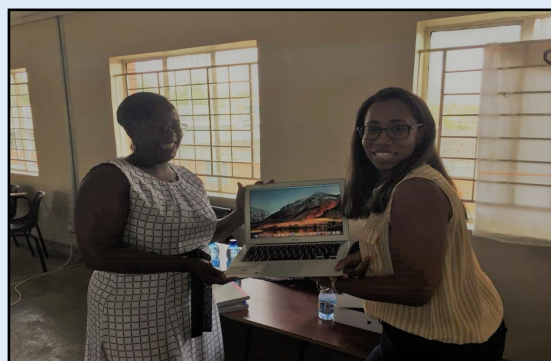
The main Malawi SIV took place from **28-29 August**. Colleagues from both **MLW** and **UNC Project Malawi** convened in Blantyre at the MLW offices. Thank you to the eight colleagues from **UNC Project** who made the journey!

Dr. Nabila Youssouf, Dr. David Lawrence and Prof. Tom Harrison then spent some time on **30 and 31 August** at **UNC Project** in Lilongwe to meet with additional AMBITION colleagues.



It was great to have clinical colleagues from both teams in one place, providing a chance to get better acquainted during group sessions on patient enrolment, clinical management and EDC use, as well as over a meal in the Ryalls Hotel on Tuesday night.

Thank you to all colleagues for your continued hard and work and efforts during this period – **we are excited for patient recruitment to begin!**



Introducing more AMBITION Colleagues

We are happy to introduce more of our AMBITION colleagues from our Harare and Kampala sites:

Kathryn Boyd: Laboratory Manager (UoZ)

I graduated from the University of Abertay-Dundee with an MSc in Biotechnology in 1999, and I have 18 years of clinical research experience in a laboratory setting. I have coordinated capacity building and training at a national level, have helped develop study protocols, and have extensive experience in laboratory management of study protocols.

The bulk of my research activities and interests have centred on HIV and opportunistic infections. My scientific contributions have included helping to generate data that contributed to local national prevalence estimates for HIV, TB, STIs and other OIs, as well as generating some of the data that led to the development of the FDA-approved, NICE and CDC-endorsed interferon-gamma release assay (IGRA, ELISpot, and TB-SPOT). In 2013 I helped to establish the Infectious Diseases Research Laboratory (IDRL) within the Department of Medicine at UZ-CHS.

I currently manage concurrent studies within the lab and my role in the AMBITION-cm Phase III clinical trial will be to manage specimen processing activities and ensure lab data quality at UoZ).



Shepherd Mudzingwa: Study Pharmacist (UoZ)

I graduated with a Bachelors degree in Pharmacy from the University of Zimbabwe in 1997. I then worked in retail pharmacy for five years. I joined the University of Zimbabwe Clinical Research Centre as a Research Pharmacist in 2003. I have also worked as a Trial Pharmacist for the Development of Antiretroviral Therapy (ART) in Africa study. I have conducted antiretroviral research for Watoto Europe, for the Africa Research Network for the evaluation of second-line therapy, for studies seeking the reduction of early mortality in HIV-infected adults and children starting ART, and also for a study around the once daily Dolutegravir based ART in young people. I have also published and co-authored a number of research papers and abstracts since 2013.

My role within the AMBITION team is to oversee all dealings within the Pharmacy at UoZ.





Richard Kwizera: Medical Mycologist (IDI Uganda—Kampala)

I am a Medical Mycologist at the Infectious Diseases Institute, College of Health Sciences, Makerere University. I hold a Bachelors degree in Biomedical Laboratory Technology and a Masters degree in Biomedical Laboratory Sciences and Management (Makerere University), in addition to a Masters in Medical Mycology (University of Manchester). I am currently a PhD Fellow in the Department of Microbiology. I have eight years of laboratory experience with a special research interest in Diagnostics, Epidemiology and Management of pulmonary and opportunistic fungal infections.



I am highly experienced in mycology laboratory techniques and have experience in HIV, TB and fungal disease diagnosis and management. I am also attached to the Makerere fungal group investigating the outcomes of HIV patients with cryptococcal meningitis in collaboration with the University of Minnesota. I have previously been involved in translational research studying point-of-care testing for cryptococcal infections in HIV, and rapid detection of CSF sterility in HIV/cryptococcal co-infection.

My main role within AMBITION is to perform laboratory specimen processing, laboratory QA/QC and to coordinate all laboratory-related activities on the study.

Edward Mpoza: Study Doctor (IDI Uganda—Kampala)

I hold a Bachelors degree in Medicine and a Masters in Internal Medicine from Makerere University. I also completed a Fogarty Global Health Fellowship with the University of Minnesota. Currently, I work as a physician with the Meningitis research team at the Infectious Diseases Institute, Kampala, Uganda. I have previously worked as a study doctor in various clinical trials in cryptococcal meningitis.



I am interested in translational HIV research with a specific interest in cryptococcal meningitis. I look forward to the day when HIV and cryptococcal meningitis will be history.

My role within AMBITION is to provide clinical care for the patients.

Catherine Nanteza: Project Administrator (IDI Uganda—Kampala)

I hold a Bachelor's degree in Environmental Management from Makerere University, in addition to training in finance management for non-finance managers. I joined the Infectious Diseases Institute (IDI) in 2011 as an administrative assistant on the COAT study. I have since provided project administrative services to several meningitis studies within IDI.

Currently, I am the AMBITION Project Administrator for the meningitis team at IDI Kampala. My role involves providing administrative support to the team.



Leo Atwine: Trial Pharmacist (IDI Uganda—Mbarara)

I have a Bachelor's degree in Pharmacy from Makerere University, in addition to a Master's in Business Administration from Uganda Management Institute. I have 8 years of experience in clinical research as a clinical trial Pharmacist. I previously worked with the Epicentre research centre in Mbarara, where most studies focused on Malaria, TB and HIV. I also worked as the regional Pharmacovigilance coordinator for south western Uganda from 2011-2016, a regional representative for the Pharmaceutical Society of Uganda (2011 to date), in addition to currently being a member of the Medicines and Therapeutic committee. Presently, I am working within the Ministry of Health as a Senior Pharmacist. I have extensive background experience in health systems strengthening, stock management, pharmacy auditing, budgeting, training, as well pharmacovigilance and the setting up of research pharmacies. I was also a member of the ASTRO study team for the Mbarara site.

Working as a Pharmacist for the AMBITION study at the Mbarara site, my main responsibilities include overseeing randomization and the management of pharmacy research, as well as stock management and quality assurance of the trial drugs.





AUGUST AMNET STEERING COMMITTEE (SKYPE) MEETING

The second AMNET Skype Meeting of 2018 took place on 26 April 2018, attended by ten Network members.

Several new members were welcomed to AMNET. They will contribute expertise on data analysis, adult acute bacterial meningitis, paediatric meningitis, and TB-Meningitis. Discussions took place around situational analysis, harmonised screening/data collection, data sharing agreements, symposium submissions, website development, fortnightly updates, AMNET general information for Meningitis Research Foundation (MRF) and next steps.

Specific outcomes were as follows:

- Agreement to include suggested edits in IRB Letter, incorporate Data Analysis Plan into the 2-page situational analysis protocol and send to all sites for review by respective IRBs.
- Agreement to design a separate protocol and data collection tool for Epidemiology. A specific Skype call for the Meningitis Aetiology Project will be arranged.
- LSHTM confirmed that Data Sharing Agreements are needed, and a suitable template will be shared in due course now that the Data Protection Act (1988) has been replaced with the new European General Data Protection Regulation.
- Discussion took place around topics for the 9th EDCTP Forum in Lisbon (September 2018) and for the 67th ASTMH Annual Meeting in New Orleans (October – November 2018).
- Agreement to circulate funding opportunities on a monthly basis.

All in all, very fruitful discussions with a dedicated team and a clear way forward.

We are also pleased to welcome three new colleagues to the AMNET team:

Dr. Suzaan Marais is a Neurologist based at the Inkosi Albert Luthuli Central Hospital in Durban, and conducts research focussing on HIV-associated CNS infections, in particular TB-meningitis.

Dr. Emma Wall is currently an NIHR Academic Clinical Lecturer within the Division of Infection and Immunity at UCL in London. Her research interests are focused on neurological infection in HIV infected adults in low and middle income settings, with a particular focus on Adult Acute Bacterial Meningitis in sub-Saharan Africa.

We are also delighted that **Dr. Lillian Tugume**, AMBITION Study Doctor from IDI Uganda, will join AMNET to assist with data analysis.



Current EDCTP Calls



Call for Experts: EDCTP Scientific Advisory Committee

EDCTP is seeking up to 7 new experts to join its Scientific Advisory Committee as of January 2019. The role will involve provision of strategic and scientific advice to the EDCTP General Assembly and Executive Secretariat, and oversight of the scientific integrity of the EDCTP programme.

Deadline: 30 September 2018

<http://www.edctp.org/scientific-advisory-committee-of-the-edctp-association-call-for-experts/>

Grant Call: Career Development Fellowships

This prestigious call is aimed at early to mid-career researchers in Sub-Saharan Africa, and provides funding of up to €150,000 for up to 3 years.

Deadline: 27 November 2018

<http://www.edctp.org/call/career-development-fellowships-4/>

Grant Call: Ethics and Regulatory Capacities

This call funds initiatives to develop and strengthen regulatory and ethical frameworks in sub-Saharan Africa, focussing particularly on National Ethics Committees and National Regulatory Authorities. Funding of up to €300,000 is offered per project.

Deadline: 22 November 2018

<http://www.edctp.org/call/ethics-and-regulatory-capacities/>

Recent Conferences

- Dr. William Hope presented AMBITION at the **20th Congress of the International Society for Human and Animal Mycology (ISHAM)** that took place between 30 June—4 July 2018 in Amsterdam RAI, the Netherlands.
Further information on topics of discussion can be found on the website: <https://www.isham2018.org/>
- **22nd International AIDS Conference**
23-27 July 2018 (Amsterdam, the Netherlands)
Further information on topics of discussion can be found on the website: <https://www.aids2018.org/>