The Ambition-cm Trial Newsletter (Issue 8: February 2018)



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Philippa (LSHTM, London)

Timothée (Institut Pasteur, Paris)



@ambitioncm2020

Please do encourage colleagues to 'follow' us!

Happy New Year from Gaborone!

We hope that you all had a refreshing break and that 2018 has started well. At AMBITION the big news is that we have recruited our first two patients here in Gaborone. We are very excited to begin recruitment after more than a year of hard work, and look forward to getting all our other sites up and running in the near future to recruit the other 848 patients!



The good news of our first patient was shared during the face-

to-face Trials Network Meeting, which took place in Lilongwe from 30-31 January. A big thank you to Dr. Mosepele Mosepele, the Network Lead, Phum'lani and Winnie from BHP who took care of the logistics, and to the team at **UNC Project** who looked after us

We are also busy planning a week of Clinical Trials and GCP Training which will take place in Gaborone from 12-16 March 2018. We are in touch with colleagues at all African sites to determine the attendee list.

In addition, we have opened applications for two fully-funded MSc Studentships at LSHTM, for September 2018 entry.

We look forward to seeing everyone very soon at SIVs and then at the Investigators' Meeting in London from 23-24 May 2018!

Best wishes, Joe

Summary of Regulatory Submissions:

| Botswana-Harvard Partnership Botswana | SIV conducted on 8 January 2018; site open to recruitment. 2 patients have been randomised. Study team are doing a great job and learning plenty. |
|---|---|
| University of Cape Town | The protocol amendment for the Ethics Submission is being prepared. The team are responding to comments from the Medicines Control Council. |
| University of Zimbabwe | The team are responding to comments received from Ethics and from the Medicines Control Authority of Zimbabwe. |
| UNC Project Malawi PROJECT Lilongwe, Malawi | Application to the Pharmacy, Medicines and Poisons Board was submitted on 8 February 2018. The team are preparing the protocol amendment submission. |
| Malawi-Liverpool Wellcome Trust Clinical Research Programme | |
| IDI Uganda | Submissions are all in progress. |













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African Meningitis Trials Network (AMTNET) - 1st face-to-face meeting

Lilongwe, 30-31 January 2018

Biannual AMTNET meetings will be organised to help the Network to strategise, plan ahead and cover the full range of topics. The focus on at this first meeting was upon collaboration and experience-sharing between the 18 participants. The meeting aimed to develop discussion on the Network deliverables—with a specific focus on the situational analysis across all study sites—and to map the way forward.

- Dr. Mosepele Mosepele, the Network Lead, opened the meeting and welcomed the participants from all AMBITION sites. This was followed by an overview of the Network, highlighting the deliverables, milestones and achievements to date. During subsequent discussions, it became clear that there was a desire to include community and public engagement, health education work and advocacy work.
- The group enjoyed presentations from site PIs / study doctors on the country-specific situational analyses, which provided detailed and realistic impressions of current meningitis screening, diagnosis, treatment and research practices at each site. We heard from Dr.Cecilia Kanyama (Lilongwe), Dr. Henry Mwandumba (Blantyre), Dr. Mosepele Mosepele (Gaborone), Dr. Admire Hlupeni (Harare), Dr. Sumaya Sayed (Cape Town) and Dr. David Meya (Kampala). Next steps will include the production of manuscript summaries about the situational analyses, a 2-page protocol for IRBs and abstract submission to the ASTMH Conference (New Orleans, October 2018) with a view to attending in person.
- The Network website and publicity strategies were also discussed, with plenty of creative ideas provided for project communication, information distribution, feedback and stakeholder management.
- A session was held on mentorship, funding and grant opportunities, and ideas for future meningitis trials. Discussions took place on harmonised screening systems, basic diagnostic packages, development of template trial documents, data-sharing agreements, and building of links with regulatory bodies.
- We also enjoyed a tour of UNC Project and its state-of-the-art laboratories from Dr. Mina Hosseinipour and Dr. Cecilia Kanyama.

Thank you to all members for their enthusiasm and contributions. We look forward already to the next AMTNET meeting, scheduled for July 2018 in Cape Town.



















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Training Courses: Clinical Trials and GCP

Gaborone, 12-16 March 2018

We are very grateful to the University of Botswana (UoB) for providing space to facilitate these two courses. Since it was founded in 1982, UoB has been heavily involved in Botswana's national development, and places a great emphasis on high-quality teaching and research with a vision to become a leading Academic Centre of Excellence, both on a national and a global scale.



The week will commence with the Clinical Trials Course (12-14 March), which will be followed by a 2-day GCP course. We have planned a busy and varied schedule, and are in touch with PIs at all AMBITION sites to nominate attendees.

The Clinical Trials Course will be delivered by Prof. Tom Harrison from St. George's University London, and Drs. Joe Jarvis, David Lawrence and Nabila Youssouf from LSHTM. For the GCP course the team will be joined by Patricia Henley, Head of the Research Governance and Integrity Office at LSHTM. Course attendees will also be drawn from UoB and from other organisations in Botswana.

Two MSc Studentships at LSHTM, September 2018 entry

This opportunity is open to candidates from the six African partner organisations in the AMBITION consortium, who are currently working full-time or part-time on the AMBITION grant, or who are about to commence their contract.

The funding will cover a stipend, tuition fees (as part of the stipend) and the outbound and return flights to and from London. The courses available are:

| MSc Epidemiology | MSc Health Policy Planning & Financing |
|---------------------------------------|--|
| MSc Medical Statistics | MSc Medical Microbiology |
| MSc Control of Infectious Diseases | MSc Public Health |
| MSc Immunology of Infectious Diseases | MSc Tropical Medicine & International Health |



Questions? You can contact **Dr. Tshepo Leeme**

from BHP, currently undertaking an MSc Epidemiology, at tbleeme@yahoo.com.

There will be two stages to the selection process:

AMBITION PIs from each partner organisation should nominate up to two potential candidates. These candidates should email an initial application to Dr. Joe Jarvis (AMBITION PI) at Joseph. Jarvis@Ishtm.ac.uk and to ambition@Ishtm.ac.uk by Wednesday 28 February 2018. The application should consist of:

- A CV
- A covering letter of no more than 1,000 words, setting out:
 - The candidate's motivation for applying to their chosen MSc
 - Their suitability for the course, drawing upon their previous education and experience
 - How completion of the MSc will assist their current role, their career, and benefit the AMBITION study
- A professional and character reference from the relevant AMBITION PI

The AMBITION Trial Management Group will assess applications and in early March will select two candidates to apply formally to LSHTM by Wednesday 4 April 2018.

We look forward to receiving applications!













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Investigators' Meeting 2018

London, 23-24 May 2018

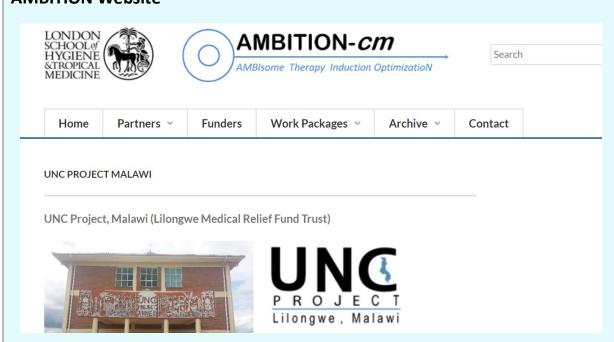
This year the meeting will take place in Woburn House Conference Centre, not far from LSHTM. There will also be the opportunity to visit LSHTM.

All flights are now booked, and accommodation has been reserved at Premier Inn Kings Cross.

Philippa will be in touch closer to the time about airport transfers, local travel for UK and French delegates, and about meal choices. She is already liaising with colleagues about paperwork for visa applications; please do get in touch if you have questions or requirements that she can assist you with.



AMBITION Website



The WordPress website is hosted through LSHTM, and is currently under development. The WP1 (Clinical Trial) pages will contain links to the latest version of the study protocol (with previous versions archived elsewhere on the website) and to the Clinical, Lab and Trial Management Work Practice Documents.

The African Meningitis Trials Network (WP4) section will transfer to a standalone website after the completion of the AMBITION project in 2020, and Philippa and Phum'lani are working together on an initial build of this section.

Please don't hesitate to contact Philippa at any point if you have suggestions or comments.













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New AMBITION colleagues

Over the last weeks and months, new colleagues have joined the AMBITION teams at various sites. We are pleased to introduce some of them here!

Malawi Liverpool Wellcome Trust Clinical Research Programme (MLW):

Dr. Melanie Alufandika: Lead Study Physician

I work at MLW as the lead study physician and coordinator of the trial here at our site in Blantyre.

I hold an MBBS from University of Malawi and have almost completed my MSc in Clinical Trials from the London School of Hygiene and Tropical Medicine.

I have 3 years of prior experience in clinical research from my work as study physician and coordinator on a HIVassociated TB clinical trial evaluating the impact on mortality of urine based diagnostics. I have a keen interest in respirology, HIV and TB, and I hope to undertake postgraduate clinical training in Internal Medicine in the near future.



Dr. Eltas Dziwani: Study Physician

I obtained my MBBS from the University of Malawi College of Medicine in 2008, and an MSc in Public Healtth from LSHTM in 2014. I have a wide range of clinical experience; I completed an internship at QECH in 2010, following which I worked at the rural Chikwawa District Hospital, managing clinical services. After this I worked for four years as a District Medical Officer for the Blantyre District and Blantyre city, where I was in charge of managing the primary health care services and disease control programmes. In 2015 I returned to QECH to take up a post as a Medical Officer in the Internal Medicine Department, where I am continuing my specialist training in internal medicine.



Ebbie Gumbi Gondwe: Lead Research Nurse

I have worked as a research nurse for 12 years in various clinical trials, including the ACTG, HPTN and MTN studies, and have a further two years of experience in Nursing and Midwifery. In particular, I have been working as a senior research nurse in cryptococcal meningitis clinical studies since 2013, including in the ACTA study from April 2013 to May 2017.

I have special interests in counselling and Health Education, and I have just completed a Bachelor Degree in Public Health to further these interests. My main responsibilities in AMBITION are to consent study participants, provide general nursing care (including clinical monitoring), administer study medications, complete Case Report Forms and follow up participants to ensure minimal loss to follow up. I also provide general oversight to ensure retention of participants.



Wezi Newa Chimang'anga: Research Nurse

I joined the AMBITION team in July 2017, with eight years' experience in research at MLW, where I worked across various studies and sites inlcuding in Chikwawa, Zomba and here in Blantyre. I hold a diploma in nursing which I obtained at Mulanje College of Nursing, Malawi, and am currently pursuing a Bachelor's Degree in Public Health in Malawi.















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Malawi Liverpool Wellcome Trust Clinical Research Programme (continued):

Tipatseni Chimphambano: Research Nurse

Prior to joining MLW in 2014, I worked on clinical trials for 7 years with the Malawi College of Medicine-John Hopkins Research Project. In addition to my role as Research Nurse, I was also responsible for quality control. Alongside my responsibilities as a Research Nurse on AMBITION, I am undertaking training as a study monitor, where I monitor a range of studies here at MLW.



Christopher Kukacha: Laboratory Technician

I studied Biomedical Sciences at Malawi College of Health Sciences, following which I joined the Malawi College of Medicine in 2011 to work on the iLins project. I took up my role at MLW in 2013 as a study lab technician on the ACTA trial.

I am responsible for processing samples from AMBITION participants here at the Blantyre site.



Infectious Diseases Institute, Uganda—Mbarara Hospital

Dr. Conrad Muzoora: Site PI

I am a HIV physician-scientist with formal training in clinical research. I completed my Masters in Internal Medicine at Mbarara University in 2008, following which I started a five-year fellowship in clinical research with the University of California San Francisco.

I have been involved in HIV care and research for the last ten years, and have special interests in Tuberculosis (TB) and Cryptococcal Meningitis (CM). My main research goals focus upon improving the diagnosis and treatment of TB and CM, particularly in persons living with HIV. I have conducted five clinical trials involving CM, and several other projects involving HIV and TB.



Dr. Edwin Nuwagira: Study Doctor

I hold a Bachelors Degree in Medicine and a Bachelors in Surgery (MBCh.B), and am also a final year candidate of Master of Medicine in Internal Medicine at Mbarara University of Science and Technology. I worked as a research medical officer for the ASTRO trial, on Phase II in Mulago Hospital and Phase III in Mbarara Hospital. My main interests lie in infectious diseases research, and from my mentors (Conrad and Kabanda) I hope to do much more in HIV and opportunistic diseases research.



As a study doctor, my main duties involve patient enrolment, sample collection, inpatient care, and outpatient follow up.

Simpson Nuwamanya: Study Nurse

I hold a Master of Public Health from Mbarara University of Science and Technology. I have worked as a Research Officer on a number of HIV-related clinical trials under the Medical Research Council / Uganda Virus Research Institute (MRC/UVRI). I am currently working on two clinical trials (ASTRO and C-ASSERT Studies) as site coordinator, and am particularly interested in the synergy between infectious diseases research and practice.













