The AMBITION-cm Trial Newsletter (Issue 28: March 2020)

AMBITION-cm AMBIsome Therapy Induction OptimizatioN

In this Issue:

- Recruitment Update
- COVID-19 Update
- 600th Participant Recruited
- IDI (Kampala site) Recruits 200th **Participant**
- Blantyre Monitoring Visit (3-7 March
- New AMBITION colleagues

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Nabila and David (LSHTM, Gaborone)

Philippa (LSHTM, London)

Timothée (Institut Pasteur, Paris)



@ambitioncm2020

Please do encourage colleagues to 'follow' us!



Cheusisime Kajanga (Laboratory Technician) retrieving stored samples from the MLW Pharmacy freezer, on a recent monitoring visit to the Blantyre recruiting site (3-7 March)

Greetings from Gaborone!



It has certainly been a challenging month. In light of recent COVID-19 developments, we unfortunately anticipate major disruptions to trial activities for the foreseeable future. More detailed information can be found on Page 3. Even in these uncertain times, we remain grateful to colleagues across all sites who continue to work tirelessly on AMBITION. We managed to enrol 41 participants in the past month alone, bringing our total to 623 participants recruited to date.

We also recruited our 600th participant on Thursday 12 March. Many congratulations to the **UCT team** for doing the honours. Well done also to the IDI Uganda team in Kampala, who enrolled their 200th participant on the same day! More details on Page 3.

The team at MLW kindly hosted Drs. Nabila Youssouf and David Lawrence for a scheduled monitoring visit from 3-7 March. Head over to Page 4 to read more.

We also introduce two further AMBITION colleagues. Mike Ssemusu joined the Mbarara team as a Study Nurse in September 2019. Please also welcome Dr. Lee-Ann Davids, who joined the **UCT** team as a **Medical Officer** earlier this month. Learn a little more about Mike and Lee-Ann on Page 5.

Rest assured, we will continue to support our AMBITION colleagues in any way possible over the coming months.

Best Wishes,

Joe













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Recruitment Update (as of 31 March 2020):

We are happy to share updates on participant recruitment numbers at each site:

Botswana-Harvard Partnership (Gaborone)



The latest participant in Gaborone was recruited on 22 March 2020

University of Cape Town: Mitchells Plain Hospital and Khayelitsha Hospital



The latest participant in Cape Town was recruited on 11 March 2020

University of Zimbabwe (Harare)



The latest participant in Harare was recruited on 23 March 2020

UNC Project Malawi (Lilongwe)

Malawi-Liverpool Wellcome Trust Clinical Research Programme (Blantyre)





The latest participant in Lilongwe was recruited on 20 March 2020



The latest participant in Blantyre was recruited on 30 March 2020

IDI Uganda (Kampala)

IDI Uganda (Mbarara)



The latest participant in Kampala was recruited on 13 March 2020



The latest participant in Mbarara was recruited on 24 March 2020













TOTAL: 623 (73%)

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COVID-19 Update

Unfortunately, it is now clear that the COVID-19 pandemic is going to have a major impact on AMBITION operations over the coming weeks and months. Where possible, the TMG would favour continuing recruitment for now. However, we do realise that local situations may quickly make this very difficult, and indeed clinical research has already been halted in some countries. As several scheduled monitoring visits have been cancelled, David, Nabila, and Timothée will now assist all sites remotely as best they can.

AMBITION budgets will of course cover the costs of any masks, eye protection, aprons/gowns and other protective materials and equipment that study teams will need to work safely and in line with local guidelines.

If recruitment is halted, plans will need to be made to follow up existing patients appropriately and to ensure that they are receiving the required medications and monitoring. The TMG will obviously support in any way we can. We are also maintaining close contact with our Project Officer at EDCTP as developments unfold.

Thank you all again for your continued hard work and for your patience in these trying circumstances.

600th Participant Recruited

On a more positive note, we are very happy to share the news that we recruited our **600th AMBITION trial participant** earlier this month. Many congratulations to the team in **Cape Town**, who did the honours on **Thursday 12 March**.

Recruitment across the consortium has been particularly high this month, and we would like, once again, to thank colleagues across all sites for their hard work during the first three months of 2020. The 600-participant milestone achievement would not have been possible without your collaborative efforts.





IDI Kampala Recruits their 200th Participant

200

A special shout-out to our **IDI colleagues** at the **Kampala** recruiting site, who enrolled their **200th participant** on **Thursday 12 March**.

Many congratulations!















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Monitoring Visit in Blantyre: 3-7 March 2020

Prof. Henry Mwandumba and the rest of the AMBITION team at MLW warmly welcomed Dr. Nabila Youssouf and Dr. David Lawrence from 3-7 March for a monitoring visit of the recruiting site in Blantyre.



It was a great opportunity for Nabila and David to work closely with MLW colleagues to assist with laboratory checks, review various study documentation and provide support with the EDC following some routine updates.

Unfortunately, this was the last scheduled face-to-face AMBITION monitoring visit for the next few months.

We are therefore happy to see that it was a successful one!



Dr. David Lawrence assisting **Cheusisime Kajanga (Laboratory Technician)** with an AMBITION
sample check on Wednesday 4 March







Christopher Kukacha (Laboratory Technician) and Dr. David Lawrence conducting an MLW laboratory check on Thursday 5 March













The AMBITION-cm Trial Newsletter

(Issue 28: March 2020)



New AMBITION Colleagues

Mike Ssemusu, Study Nurse (IDI Mbarara)





I graduated with a diploma in Nursing from Bishop Stuart University in Uganda. I began my career working as a Volunteer Nurse on a number of studies including ADEPT, RifT and CCM. During this time, I gained considerable experience in both clinical trial research and in the management of patients with HIV, TB and cryptococcal meningitis.

My primary interests lie in exploring the psychological effects associated with the counselling and management of patients with infectious diseases.

My main responsibilities on AMBITION are to screen and consent participants, provide general nursing care (including clinical monitoring), administer study medications and undertake sample and data collection. I also oversee outpatient follow-up of study participants.

With the mentorship of Dr. Edwin Niwagyira and Dr. Conrad Muzoora, I hope to gain further experience in this field and develop my career in infectious disease research and clinical trials.

Dr. Lee-Ann Davids, Medical Officer (UCT)





I graduated with an MBBS in 2007 from the University of KwaZulu Natal, Nelson R. Mandela School of Medicine. I also have postgraduate diplomas in Obstetrics (2010) and in HIV Medicine (2013) from the Colleges of Medicine of South Africa (CMSA). I completed my Masters in Public Health from the University of the Western Cape (UWC) in 2017, and for my research project I investigated factors that influence adherence to ART amongst adolescents.

I have 7 years of post community service experience in infectious diseases, primarily in HIV and TB medicine in a primary health care setting.

I also have experience in both drug-susceptible and drug-resistant tuberculosis trials. I served as a District Manager for an NGO in Cape Town on the APACE programme, supporting 19 health care facilities to reach their targets as they pertain to the UNAIDS 90/90/90 treatment goals.

I currently have the privilege of working alongside Prof. Graeme Meintjes and the UCT team as a Trial Doctor on AMBITION in Cape Town. I am truly grateful for this opportunity.











