



AMBITION-cm

AMBIsome Therapy Induction Optimization

AMBITION NEWS

The AMBITION-cm Trial Newsletter

Issue 10, June 2018

LONDON SCHOOL OF HYGIENE AND TROPICAL MEDICINE ~ ST. GEORGES, UNIVERSITY OF LONDON ~ LIVERPOOL SCHOOL OF TROPICAL MEDICINE ~ UNIVERSITY OF LIVERPOOL ~ INSTITUT PASTEUR ~ BOTSWANA-HARVARD PARTNERSHIP ~ UNIVERSITY OF ZIMBABWE ~ MALAWI-LIVERPOOL-WELLCOME TRUST CLINICAL RESEARCH PROGRAMME ~ UNC PROJECT MALAWI ~ UNIVERSITY OF CAPE TOWN ~ INFECTIOUS DISEASES INSTITUTE UGANDA

TEAM EMAIL ADDRESS: AMBITION@LSHTM.AC.UK

Greetings from Gaborone!

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



We continue to steadily screen patients in Botswana, and have also started to plan Site Initiation Visits (SIVs) - the first of which is scheduled to take place in Cape Town in the next few weeks.

We also ran a successful Investigators' Meeting at Woburn House in London from 23-24 May 2018. It was a lovely couple of days spent talking about all things AMBITION related - a great opportunity for the entire team to congregate and share their experiences, as well as important information about site updates. We now look ahead to our next SIV in Cape Town!

Best Wishes,
Joe



twitter

[@ambition2020](https://twitter.com/ambition2020)

Please do encourage
colleagues to 'follow' us

In this Issue:

- * Updates on Ethical and Regulatory Submissions
- * Prof. David Lalloo's Promotion
- * New Members of Staff
- * Investigators' Meeting - London, 23-24 May 2018
- * GDPR Update
- * SIVs and planned dates



Dr. Chimwemwe Chawinga and Dr. Cecilia Kanyama discussing what's coming up in this issue of the AMBITION Newsletter...



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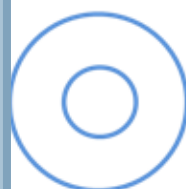


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Regulatory Submissions

BOTSWANA-HARVARD PARTNERSHIP



Site open to recruitment. 14 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. MCC approval was granted on Monday 4th June. We now have all Regulatory approvals. 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 August 2018.

Congratulations!

Prof. David Lalloo

We would like to take this opportunity to extend our warmest congratulations to Professor David Lalloo, one of our Senior Investigators based at LSTM, on being appointed as the new Director of Liverpool School of Tropical Medicine (LSTM). We wish him all success in his new role.



New Starters

We are happy to report that a new member of staff has joined the AMBITION team. We are pleased to introduce him here:



DR KEATLARETSE SIAMISANG

I joined the AMBITION Project in May 2018. I am currently working as a part-time study doctor at BHP. I was born in Letlhakeng, Botswana. I completed my Medicine, Surgery and Medical Sciences Degrees at the University of Melbourne in 2010. I undertook a Medical Internship at Nyangabgwe Referral Hospital in 2011. I proceeded to work as a Medical Officer in Nyangabgwe Hospital from 2012 to 2013. I then enrolled as a Medical Student at the University of Botswana and switched to a Masters of Medicine and Public Health in 2018.



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Investigators' Meeting - London, 23-24 May 2018



From 23-24 May 2018, AMBITION members from our African and European sites convened in London for the 2nd Investigators' Meeting.

The meeting included 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) also met on the afternoon of Wednesday 23rd May, with those members who were not present at the Investigators' Meeting dialling in.

A short presentation was given on the new European General Data Protection Regulation (GDPR), which took effect on 25 May 2018. Our new EDCTP Project Officer, Johanna Roth, was also in attendance and shared a presentation on the EDCTP budget and priority research areas to upcoming grant calls, and answered a few questions from the team.

The meeting provided an excellent opportunity for the AMBITION team to network and update others on all the commendable work that everyone has been doing. This will prove all the more valuable as we look ahead to conducting our SIVs in the coming weeks and months.

All in all, the Meeting was a great success, as is evident from the wonderful pictures of everyone here!



EDCTP

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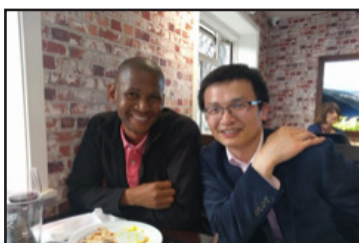
THE AMBITION-CM
TRIAL NEWSLETTER
(ISSUE 10: JUNE 2018)



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GDPR - General Data Protection Regulation

What, When and Why?

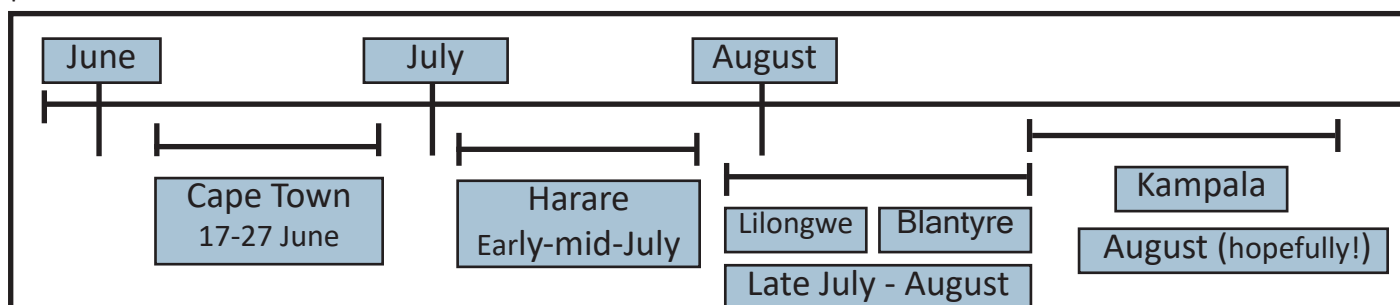
- Tightening of existing data protection regulations
- Took effect on 25 May 2018
- Strict rules for the treatment and storage of personal data
- Provides individuals with a choice as to whether and how their data is stored

- The GDPR also applies to non-EU citizens who are involved in EU-funded projects.
- Philippa updated us all during the Investigators' Meeting on the impact of these changes as we go forward with the AMBITION Project
- In the table below you can find some information outlining how we will request and store personal information for the duration of AMBITION.
- LSHTM is finalising its GDPR policy, and Philippa and Sophia will be in touch in the coming weeks with requests for action on your part.

1. Email Addresses held on file at LSHTM	Email confirmation required from each individual / recipient – can delete if requested
2. AMBITION Newsletter	
3. DOB and Passport details held at LSHTM for flight bookings	
4. Use of photos / video for newsletter / website / Twitter	Individual to sign Declaration Form if they are happy for photos etc. to be used for the duration of AMBITION
5. Salary Information of AMBITION participants held at LSHTM (for EDCTP reporting)	LSHTM computers are fully encrypted to ensure such data remains safe and confidential

Site Initiation Visits (SIVs)

We are delighted to announce that the SIVs will be taking place in the upcoming months. Please see below a provisional timeline for each site:



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