

AMBITION News

The Ambition-cm Trial Newsletter
(Issue 11: August 2018)



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@ambitioncm2020

Please do encourage
colleagues to 'follow' us!



Dr. Tawanda Zinyandu (Study Doctor) welcomes Joe
at the Harare SIV, July 2018

Greetings from Gaborone!



Thank you again to colleagues at all sites who have been working so hard on AMBITION these past weeks: whether on the final stages of regulatory submissions, preparation for patient enrolment, or indeed actively screening patients.

We are delighted that since our last Newsletter was issued, **we have opened for recruitment in both Cape Town and Harare. SIVs at both sites** took place during July. We are grateful to our fellow AMBITION team members for your warm welcome during the SIVs and for your continued efforts and enthusiasm as we kickstart recruitment.

We continue to steadily screen patients in Botswana and are happy to report that we recruited our first patient in Cape Town on 3 July 2018! Well done to the teams for their hard work, and we look forward to recruiting many more patients in the coming months.

We also look forward to opening the **Kampala and Mbarara recruitment sites** in Uganda during the SIV on 6–8 August. We then hope to have the green light for the **Blantyre and Lilongwe sites** shortly afterwards.

We would like to congratulate **Dr. Tshepo Leeme** from BHP who has completed her MSc Epidemiology exams at LSHTM and who has now returned to Gaborone to complete her summer project.

We are pleased to introduce Health Economist **Tinevimbo Shiri** from Liverpool School of Tropical Medicine, who recently joined the AMBITION team, working with Prof. Louis Niessen and Prof. Shabbar Jaffar. Welcome Tinevimbo!

Finally, we are pleased to have **survived our first phase of EDCTP financial and technical reporting!** Philippa (Financial & Administrative Project Manager) is in the process of disbursing the reimbursement for eligible spend made in Year 1 (Jan–Dec 2017) to all partners. She is grateful to financial and administrative colleagues at all sites for their patience whilst we answered the EDCTP's various queries prior to approval.

Best Wishes,
Joe



Summary of Regulatory Submissions

Botswana-Harvard Partnership



Site open. 16 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



MCC approval was granted on 4 June. Site open: we recruited our first patient on Tuesday 3 July 2018.

University of Zimbabwe



The permit for import of drugs to Zimbabwe was received on 19 June. Regulatory paperwork was submitted to MCAZ on 20 June. Site open .

UNC Project Malawi



Malawi-Liverpool Wellcome Trust Clinical Research Programme



The country-specific insurance certificate is being finalised. We expect the final stamp of approval from the Pharmacy, Medicines and Poisons Board (PMPB) once this is complete. We hope to open the two Malawian sites shortly after visiting Uganda.

IDI Uganda



The Ugandan National Drug Authority (NDA) approvals are now in place. The SIVs are scheduled for 6-8 August 2018 when we hope to open to recruitment in Kampala and Mbarara.

Departing MSc Student



As we approach the end of the UK academic year, we would like to congratulate **Dr. Tshepo Leeme**, from the AMBITION team at the Botswana-Harvard Partnership, on completing her MSc exams in Epidemiology at the London School of Hygiene and Tropical Medicine. We wish her continued success as she embarks upon her Summer Project, and all the best for her return to full-time work as AMBITION Study Doctor at BHP in September. It was lovely to have her here in London this past year, and we hope she enjoyed her studies and taste of London life (including the freezing February weather!) at LSHTM. Congratulations Tshepo and good luck with your Project!



Cape Town Site Initiation Visit

It has well and truly been the season of SIVs!

The Cape Town SIV took place from **26 June—6 July 2018** at Mitchells Plain Hospital and the University of Cape Town, South Africa. Prof. Joe Jarvis, Dr. Nabila Youssouf and Dr. David Lawrence from LSHTM and Ms. Katlego Tsholo (Research Nurse) from BHP were welcomed by the Cape Town team.

It proved to be a great visit, with lively discussions on study protocols, sharing of key information pertaining to clinical procedures and productive discussions around the AMBITION Electronic Data Capture Tool ahead of recruitment.

Although the weather may have been rather chilly, we are pleased to announce that the site **is officially open**, with our **first Cape Town patient recruited on Tuesday 3 July 2018**. All credit goes to our team in Cape Town who have been working so hard these past few months, and who continue to do so as we enter the next phase of the study.

All in all, the SIV was a great success! Well done to everyone involved—we look forward to recruiting many more patients in the coming weeks and months.



Smiles all round for the Cape Town SIV team!



SIV completion certificates for MK (Clinical Research Worker), Siphokazi (Research Nurse) and Sumaya (Study Doctor)!





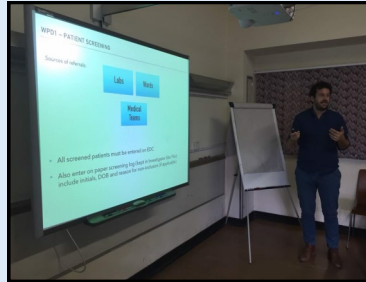
Harare Site Initiation Visit

The Harare SIV took place from **9-13 July 2018** at Parirenyatwa Hospital and The University of Zimbabwe College of Health Sciences. Dr. Timothée Boyer-Chammard (Institut Pasteur), Prof. Joe Jarvis, Dr. Nabila Youssef and Dr. David Lawrence (LSHTM) and Ms. Norah Mawoko (Study Pharmacist / Pharmacist of Record —BHP) were welcomed by the Harare AMBITION team.

They hit the ground running with presentations and discussions on Clinical WPDs and study drug administration, and took time to look in detail at the AMBITION Electronic Data Capture Tool.

It is safe to say that the SIV was a great success! We would like to take this opportunity to thank our team in Harare for their wonderful hospitality as well as to acknowledge all their hard work and preparation for the SIV.

We look forward to recruiting our first patients very soon!



Uganda Site Initiation Visit

The Uganda SIV is scheduled to take place from **6-8 August 2018**. Prof. Joe Jarvis, Prof. Tom Harrison, Dr. Nabila Youssef and Dr. David Lawrence will be visiting our AMBITION team in Kampala to conduct the SIV, and Dr. Lawrence will then spend a few days in Mbarara to meet the team there, and to be on hand for the recruitment of the first patient. Fingers crossed that all goes to plan and we will have opened both Ugandan sites to recruitment by early August!

New AMBITION Colleague

We are happy to share that a new colleague has joined the AMBITION team at The Liverpool School of Tropical Medicine (LSTM). Tinevimbo will be assisting with the Health Economics aspects of AMBITION. We are pleased to have him introduce himself here!

Dr. Tinevimbo Shiri

I am an infectious disease modeller / health economist, and studied computational and applied mathematics at the University of the Witwatersrand, South Africa. For the past seven years, I have been working on pneumococcal disease in South Africa and the United Kingdom. Before I joined LSTM, I was leading the pneumococcal disease modelling work at Warwick University, Clinical Trials Division. This work was part of the Mathematical & Economic Modelling for Vaccination and Immunisation Evaluation (MEMVIE) project that brings cutting-edge research techniques in mathematical modelling and health economics to provide complementary second opinion and advice on the effectiveness and cost-effectiveness of pneumococcal vaccination programmes in the United Kingdom.

My research interests include applying and developing statistical and data-driven computational models to better understand the dynamics of pathogens and disease control, and evaluating the effectiveness of health interventions.



EDCTP Periodic Report Approval—Year 1



We are delighted to have made it through the first EDCTP periodic report with excellent results: few rejected costs across the whole Consortium and positive feedback from EDCTP about the quality of our descriptions of costs. Philippa is so grateful to study teams and to financial / administrative colleagues from all partners for their hard work, patience and co-operation during January and February to meet

the submission deadline of 1 March 2018.

Philippa is now in the process of organising the reimbursement for eligible Year 1 spend to all partners. She also looks forward to visiting all African partners between October and January to provide informal financial support visits and to help prepare for the next reporting period!