OPTIMIZE

This is a monthly update shared with all members involved in Project Optimize, and is meant to provide a short update of major achievements, challenges, and plans for the future. Please submit any inputs to Celicia Serenata before the 1st Wednesday of every month.

Please note that some of the information in this update are confidential, so please do not share outside of OPTIMIZE.

Major Achievements from September 2016

LOW-DOSE DARUNAVIR STUDY, Wits RHI

- 120 participants were screened, and 80 enrolled in the study. Another 28 have already been screened and are awaiting enrolment.
- There was a brief 4-day stoppage recommended by the external study monitor after noticing a minor discrepancy between the protocol and the consent form. MCC was notified, and with them turning around the amendment in record time, enrolment resumed.

ADVANCE STUDY, Wits RHI

- Following multiple communications, the language for the contract between Wits RHI and Gilead was finalised. The final contract for signing is awaited.
- ViiV has approved the final ADVANCE protocol, and can move to contracting next. Drug delivery is not anticipated before end November 2016.
- Wits RHI adjudicated the tender for the CRO and for the drugs to be procured for the study. Contracting will happen in late October for the CRO, and for the drug procurement after a UNITAID Board decision on the grant is received.
- Final changes were made to the ADVANCE protocol – and version 2 can now be resubmitted to Ethics and MCC as an

Upcoming Events

6 October 2016: Francois Venter presents at the *AWACC Conference (Annual Workshop on Advanced Clinical Care – HIV)* on Challenges to Test and Treat, and ART Optimization

13-14 October 2016: Francois Venter is a panel speaker at the *Controlling the HIV Epidemic with Antiretrovirals* conference in Geneva, Switzerland.

Important Contacts

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amendment.

MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP

- ICAP submitted all materials and tools to the Columbia University IRB for OPTIMIZE country needs assessments. Approval was received on September 2, 2016.
- All interviews for the country needs assessment in South Africa were completed. With a huge thanks to Celicia, we were able to conduct 20 interviews in 2 weeks!
- The Impact Overview was finalized (pending final cost savings information from MPP) and has been shared with a graphic designer for formatting.
- ICAP held conference calls to introduce the project to ICAP's Kenya team and has made plans, in collaboration with USAID DC, to connect with the Kenya USAID Mission to discuss the project in Kenya further.
- ICAP introduced the project to ICAP's Mozambique team and initiated communication with USAID to identify the appropriate Mission contacts for introducing the project in-country.
- In an effort to broadly share resources about and promote planning for the introduction of optimized ARVs, ICAP initiated the development of a note and package of materials to share with all ICAP country teams.

EFAVIRENZ 400mg TB PK STUDY, Mylan (St. Stephen's AIDS Trust)

UK

- The Site Initiation Visit (SIV) was hosted on the 29th of September.
- The UK site is pending local approval. Once this has been obtained, the site will be approved to commence recruitment.
- Recruitment is anticipated to be a challenge. Recruitment may take place at a rate of 2 participants/month.
- Preliminary data is anticipated to be available by April 2017 (dependent on recruitment).

Uganda

- The ethics committee approval from the UK, coupled with study documents, was sent to the team in Uganda on the 23rd of September to initiate the submission process.
- The study document mirrors the pregnancy study. As such, the aim is for the approval process to be expedited. This will be discussed with the Uganda PI during the first week of October.

EFAVIRENZ 400mg PREGNANCY PK STUDY, Mylan (St. Stephen's AIDS Trust)[1]

UK

- 5 women have been enrolled; three of which have finalized results.
- The first Trial Steering Committee meeting is to be held on the 4th of October to review the viral loads and EFV levels of the first 4 weeks of data.
- It is anticipated that the recruitment target of 7 participants will be met.
- Preliminary data is anticipated to be available for 6/7 women by Q1 2017.

[1] This study is not funded through OPTIMIZE, but is included here as a point of interest

Uganda

- The site is expected to receive approval by the first week of October. Patients have been identified and are ready for enrolment as soon as approval is provided.

NANOTECHNOLOGY, University of Liverpool

- Chemistry have now provided Pharmacology with seven darunavir and darunavir/ritonavir SDNs for testing, including 70% weight loaded drug at 6:1 and 8:1 ratios. A variety of cell lines are currently being grown for pharmacological testing of these SDNs to be completed.
- Chemistry is working on atazanavir SDNs investigating reproducibility and stability as well as darunavir/ritonavir/dolutegravir SDNs, although this combination is in the very early stages.

Major Plans for October 2016

LOW-DOSE DARUNAVIR STUDY, Wits RHI

- Continue enrolment, and begin the process of securing post-trial access

ADVANCE, Wits RHI

- Conclude contracts with ViiV and Gilead
- Submit version 2 of the protocol to Ethics and MCC
- Secure approvals from the district health authority to conduct the trial

MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP

- Compile and share all findings from the South Africa Country Needs Assessment
- Advertise for Kenyan staff, if appropriate, based on conversation with USAID Mission
- Begin discussions with USAID Mission in Mozambique to introduce the project
- Initiate the development of a web-based Country-Level Impact Overview tool
- Draft the advocacy strategy document and share with Workstream colleagues for review
- Refine and finalize the note and package of materials on optimized ARVs to share with ICAP country teams
- Continue Market Shaping Strategy summary for DTG, TAF, EFV400 and DRV/r and share findings to date with PSM.
- Synthesize Landscape Analysis into shorter publication and appropriate fora (journals and/or advocacy meetings)

Staffing Changes

- Dr. Veronique Bortolotti has resigned from her position at ICAP.
- Ms. Deepa Rajamani will start as the Market Access Coordinator at ICAP on October 10th, 2016.
- Wits RHI interviewed candidates for the Project Manager/Coordinator position – the preferred candidate declined after a better counter-offer from her current employer. We will

now pursue the 2nd selected candidate
- ICAP is hiring a Product Introduction Technical Advisor. The link to the job description is here.

Outputs

List any articles, manuscripts submitted for review; abstracts submitted; presentations given. (Also provide electronic version of such products for the Dropbox)

- Michelle Moorhouse, 19 September 2016: *Optimising ART for epidemic control*, at HIV Clinicians Society of Kenya and NASCOP Joint Conference, Nairobi, Kenya
- Michelle Moorhouse, 19 September 2016: *Improving outcomes*, at HIV Clinicians Society of Kenya and NASCOP Joint Conference, Nairobi, Kenya