

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 Celia 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 AUGUST 2016

LOW-DOSE DARUNAVIR STUDY, Wits RHI

- As of 31 Aug 2016, 81 participants have been screened, and 65 enrolled (total study population = 300)
- 43 first visits conducted as of 31 Aug 2016, with retention at 100%
- Recruitment strategies continue to be reviewed and amended where necessary to improve participant numbers

ADVANCE STUDY, Wits RHI

- Gilead agreed to donate the additional 480 bottles of Descovy (F-TAF) required for the study. This was necessitated through the addition on an additional 60 children to the overall study. At this point the main stumbling block to receiving drug is related to a contractual clause that requires clarification. Wits RHI is in constant contact with Gilead on this.
- As for the donation from ViiV, the contractual process can only start once the internal ViiV reviews have been completed. ViiV have asked for additional revisions to the protocol.
- Wits RHI published the tender for both the CRO and the drugs to be purchased for ADVANCE. The due date for



Upcoming Events

5-7 September: Francois, Celia and Mary to meet with University of Liverpool, St. Stephen's AIDS Trust, i-Base and ViiV (Liverpool and London, UK)

Important Contacts

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tender submissions is mid-September, and will be adjudicated late September.

- ADVANCE received Wits ethics (HREC) approval on 2 September and MCC approval on 8 August. With these approvals, we can now apply to the District Research Committee (City of Johannesburg) and the provincial research committee (GDoH) for approval. Thereafter we will submit the revised protocol as an amendment to both HREC and MCC.

DEMAND CREATION AND PRODUCT INTRODUCTION, ICAP

- Landscape analysis revised and updated, incorporating feedback from consortium partners. CII (USAID) introduced ICAP to R4D who, under a contract for Gates, are conducting a similar exercise.
- Plans developed to introduce the project in Kenya and Mozambique as focus countries for Y2, and other countries to conduct research for case studies
- Market Shaping Strategy summary updated to incorporate feedback from CII.
- Impact Overview revised to include feedback from CII and shared with CHAI and MPP for review; framework to showcase country-level impact refined
- Case Study outlines updated to integrate feedback from CII; initial interviews with ICAP and CHAI country offices conducted and additional interviews scheduled
- Recruitment of potential interviewees for South Africa country needs assessment conducted by Wits RHI
- First Workstream 3 coordination call held with all consortium partners to deliberate and refine activities for Y2

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

- Responses to the queries made by the Ethics Committee and Health Research Authority have been submitted. The estimated date of approval is 19 September 2016. The study will aim to start recruitment in London at the end of September (**pending approval**). Preliminary results should be available by April 2017; final results anticipated by September 2017
- The Uganda site will not be submitted for ethics until approval from the Ethics Committee in London is received; anticipate ethics submission to take place in October 2016. Approvals in Uganda can take up to 8 months, so it is difficult to estimate timelines. Anticipated completion date is November/December 2017.
- The objective will be to prepare an abstract for CROI 2018.

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

- At the London site, 4 patients have been enrolled, with 3 anticipated to be screened in September 2016. The site should meet the target of 7 women by end September. Results of 6/7 women are expected by Q1 2017.

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

- The Uganda site received ethics approval in July 2016. Recruitment is expected to start in September 2016, and should be complete by June 2017 (aim is to recruit 2 patients per month).
- Depending on the Uganda enrolment rate, it is anticipated than at abstract will be submitted for IAS (Paris, July 2017)

UNITAID PROJECT PLAN

- Wits RHI submitted the final documents for the grant from UNITAID. The UNITAID funding will cover scientific studies (3rd arm of ADVANCE, 3 PK studies through St. Stephen's AIDS Trust and University of Cape Town), a costing paper, and demand creation activities (with TAC, South African HIV Clinicians Society, and i-Base). Internal reviews have been completed, and the only remaining step is Board approval – which is expected in October.

COLLABORATION

- Prof. Francois Venter and Prof. Anton Pozniak (an ADVANCE Technical Advisor) have been asked to be members of the ACTG Antiretroviral Therapy Strategies External Advisory Group. This will provide additional opportunities to share information on OPTIMIZE and explore further cooperation opportunities.

MAJOR PLANS FOR SEPTEMBER 2016

LOW-DOSE DARUNAVIR STUDY, Wits RHI

- Additional Research Nurse starts 1 September, which will assist with recruitment
- To expand recruitment sources in an effort to meet accrual recruitment target
- First Site Monitoring Visit with Lesley Burgess scheduled for 19-21 September

ADVANCE, Wits RHI

- Finalise the protocol revision in order to submit to ViiV and Gilead (important steps in order to trigger contracting and drug shipment), as well as to MCC and HREC.
- Finalise an advocacy piece for the South African Medical Journal (SAMJ) on the benefits of DTG and TAF.

NANOTECHNOLOGY, University of Liverpool

- Pharmacology analysis of nano-DRV

DEMAND CREATION AND PRODUCT INTRODUCTION, ICAP

- Conduct country-level needs assessment in South Africa
- Follow-up with consortium partners based on conversations from Workstream 3 coordination call

- Finalise Impact Overview with inputs from MPP and CHAI
- Engage ICAP Kenya country office to discuss strategy for local product introduction
- Continue to collect data for case studies
- Continue Market Shaping Strategy summary

STAFFING CHANGES

- ICAP is hiring a Product Introduction Technical Advisor. The link to the job description is [here](#).
- Wits RHI is conducting interviews for a Project Coordinator to assist with overall coordination of all USAID and UNITAID-funded activities

OUTPUTS

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

- Francois Venter, August 2016: Article for Positive Magazine, <http://www.positivemagazine.co.za>

Below are presentations from IAS2016 that were not included in the previous update.

- Francois Venter, July 2016: Optimizing HIV Therapy in Resource Limited Settings, Global HIV Forum (IAS pre-meeting)
- Francois Venter, July 2016: Innovations in HIV Treatment: What the Future Holds, Symposia Session (Synergistic Epidemics: New Drugs, New Challenges)
- Francois Venter, July 2016: Access and Adherence: Cultural, Social and Logistical Issues, Session (Meeting Patient Needs and Achieving Durable Treatment Success with Antiretrovirals: Contemporary Challenges)
- Francois Venter, July 2016: Chair of Session: Understanding the Interplay between HIV and Ageing, NCDs and Malignancies: Adapting Our Responses from the Individual Person to Global Policy Level
- Francois Venter, July 2016: What is the Role of CD4 Count in a Large Public Health Antiretroviral Programme, Session (HIV Patient Management)