

# OPTIMIZE

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*This is a monthly update shared with all members involved in 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 1<sup>st</sup> Wednesday of every month.*

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## MAJOR ACHIEVEMENTS FROM JANUARY 2017

### UNITAID GRANT

- All agreements have either already been signed, or are in the process of being signed. The only outstanding agreement still to negotiate is with University of Cape Town.

### LOW-DOSE DARUNAVIR STUDY, Wits RHI

- As of 3 February, there were 252 participants screened and 201 enrolled in the low-dose DRV (WRHI052) study
- Recruitment strategies continue to be reviewed and amended where necessary to improve participant numbers
- Retention:
  - Visit 1 Completed = 165/165 (100%)
  - Visit 2 Completed = 123/123 (100%)
  - Visit 3 Completed = 55/57 (96%)

### ADVANCE STUDY, Wits RHI

- ADVANCE HAD STARTED! After many months of hard work, the first participants were screened on Monday 16 January.
- The South African Medical Journal advocacy piece on ADVANCE that was published online on 28 December 2016 continues to generate good publicity for ADVANCE. The Minister of Health from Namibia responded to Francois indicating that they are very interested in introducing a DTG-containing regimen in 2018/19.
- The electronic study database went live at research sites on 1 February, meaning that sites can electronically randomise participants onto the study in real-time, without using a laborious manual randomisation process.
- Study information pamphlets are undergoing design and approval – these will be a beneficial tool to aid CAB members and recruitment teams in support of their recruitment efforts.



### Upcoming Events

13-16 February: CROI 2017, Seattle, USA

### Important Contacts

Celia Serenata, Wits RHI, [cserenata@wrhi.ac.za](mailto:cserenata@wrhi.ac.za) or Skype: Celicias

Averie Gachuhi, ICAP, [ab3857@cumc.columbia.edu](mailto:ab3857@cumc.columbia.edu)

Jo Sharp, University of Liverpool, [joanne.livermore@liverpool.ac.uk](mailto:joanne.livermore@liverpool.ac.uk)

Kellen Thomas, Mylan, [Kellen.Thomas@mylan.com](mailto:Kellen.Thomas@mylan.com)

Lauren Jankelowitz, SAHCS, [lauren@sahivsoc.org](mailto:lauren@sahivsoc.org)

Noma Rangana, TAC, [noma.rangana@tac.org.za](mailto:noma.rangana@tac.org.za)

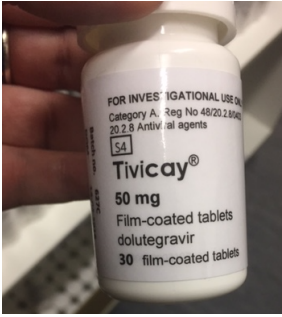
Polly Clayden, HIV i-Base, [polly.clayden@i-base.org.uk](mailto:polly.clayden@i-base.org.uk)

Emily Hutton, SSAT, [Emily.Hutton@ststcr.com](mailto:Emily.Hutton@ststcr.com)

Carolyn Amole, CHAI, [camole@clintonHealthAccess.org](mailto:camole@clintonHealthAccess.org)

Yao Cheng, MPP, [ycheng@medicinespatentpool.org](mailto:ycheng@medicinespatentpool.org)

- As of 3 February, we had screened 26 participants, of which 23 are eligible, and 5 have been enrolled.



## MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP

### *Country-level Activities:*

- Liaised with the country team in Mozambique to prepare for the needs assessment; continued to refine the summary report and accompanying presentations for the South Africa needs assessment
- Identified staff to coordinate the workstream 3 activities in Kenya
- Engaged ICAP's country teams in Cote d'Ivoire, Zimbabwe, Kenya, DRC and Mozambique to consider OPTIMIZE in COP planning
- Continued discussions in Mozambique between ICAP's country office and the MOH to identify opportunities for OPTIMIZE

### *Documents and Tools Development*

- Shared the Impact Overview with USAID for final review – awaiting final feedback
- Continued discussions with a web development firm to develop a landing page to showcase ICAP's publications and documents
- Completed the market shaping strategy and shared it with USAID for review
- Shared case study concepts with USAID-CII and received feedback from their procurement and supply chain colleagues – will need to develop an alternative concept for one so as to not duplicate work. Also initiated contact with ICAP country teams in preparation for the case study interviews

### *Collaborations*

- Participated in a call with CHAI, WHO, USAID and UNITAID to discuss ICAP's role as WHO rolls out enhanced monitoring tools

### *Early Adopter/Pilot Assessments*

- Refined the concept for enhanced monitoring of DTG in Kenya to incorporate use of existing M&E systems and provide rapid feedback to decision-makers

## *EFAVIRENZ 400mg TB PK STUDY (SSAT062), Mylan (St. Stephen's AIDS Trust)*

### UK

- Recruitment: This is a challenging cohort to recruit, and the rate of recruitment is estimated at 2 participants/month)
  - Cohort 1: 2 screened, 1 enrolled and completed baseline visit on 6 December
  - Cohort 2: 4 screened, 3 enrolled and completed baseline visit on 9 January – 1 withdrawal
  - Cohort 3: 3 screened, 2 enrolled and completed baseline visit on 23 January
  - Cohort 4: 2 screened, baseline visits due on 13 February
  - Total to date: 11 screened, 6 enrolled and 1 withdrawal
- Data management/analysis
  - Preliminary UK data to be analysed in April 2017 – analysis will include all data available at the time
  - Aim to submit an abstract (with available data) for CROI 2018

### Uganda

- Approvals:
  - Scientific Review Committee (SRC): Protocol v2.0 & PIS/ICF (v2.0 & PG v1.0) was presented to the site's SRC. The presentation was successful, with only minor comments
  - Updated PIS-ICF v3.0 is currently being translated and IRB submission pack is being completed

## *EFAVIRENZ 400mg PREGNANCY PK STUDY (SSAT063), Mylan (St. Stephen's AIDS Trust)<sup>1</sup>*

### UK

- Recruitment:
  - 6 women have been enrolled; 2 potential patients to be recruited by mid-February and 1 by mid-March 2017
  - The 2<sup>nd</sup> Trial Steering Committee to take place as soon as the viral loads and EFV levels of the first 4 weeks of 15 participants will be available; date to be confirmed, but estimated for end February/early March
  - The UK site is amending the target from 6- 7 participants, to 6-9, and moving the end of recruitment from March to May 2017. The overall target for both sites (UK and Uganda) is 25.
- Analysis:
  - Preliminary data for 6/7 women is estimated by Q1 2017

### Uganda

- All approvals are in place, and the site is doing well
- Recruitment:

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

- 18 participants have been screened, 9 enrolled, and 2 potential participants have been identified (screening scheduled for the 2<sup>nd</sup> week of February): 8 screen failures and 1 patient withdrawn
- Recruitment is going well, and the site is confident to achieve ¾ of the target by end February (13-14 participants)

### **NANOTECHNOLOGY, University of Liverpool**

- *In vivo* work was completed on two formulations of DRV/r at different ratios
- Processing of tissue and plasma samples from these *in vivo* studies will show the plasma profile over time, and tissue distribution of drug
- Cell lines grown and confluent to produce transwells for *in vitro* testing of ATV formulations
- Completed the information for a Infographic that summarises nanoformulation of ARVs and highlights the advantages of cost reduction, increased bioavailability and impact on treatment access. This is now ready for submission to UNKNOWN for design.

### **MARKET ACCESS, Medicines Patent Pool (MPP)**

- Two of MPP's licensees have applied for WHO prequalification and USFDA approval of the DTG 50mg tablet – making a total of 4 MPP licensees to have filed the product
- Another MPP licensee has applied for WHO and USFDA approval for the combination product TDF/3TC/DTG

### **DEMAND CREATION AND COMMUNITY ENGAGEMENT, HIV i-Base**

- Producing a bumper edition of *HTB South* to be distributed with the Southern African HIV Clinicians Society Journal in February. It is currently with the designer, and should be delivered late January or early February.
- Producing *Fit for Purpose* for distribution at the 2017 WHO Think Tank meeting before CROI in Seattle, as well as at other CROI meetings
- HIV i-Base is developing the Op-ART Trial Tracker – an online resource to track clinical trials related to optimised ART for LMIC – *please note this is not funded through OPTIMIZE*
- HIV i-Base and a TAC staff member met in London to begin initial project planning, especially around the development and design of the treatment literacy materials (see below)

### **COMMUNITY ENGAGEMENT, TAC**

- Developed a plan for the publication and launch of treatment literacy materials – the plan is to update existing materials, as well as write new materials between now and end May (e.g. updating the HIV and TB modules of "HIV in our lives", and creating new posters). Technical assistance will be provided by Polly Clayden from HIV i-Base
- The materials will be launched at the SA AIDS Conference in June 2017

### **CLINICIAN/HEALTH WORKER ENGAGEMENT, Southern African HIV Clinicians Society**

- Started establishing the expert HCW committee to guide the activities

- Commenced gathering materials for the health worker training, and have scheduled the first training (with doctors) in March
- SAHCS will be reviewing its programmes to determine how to include treatment optimisation
- Planning an article on treatment optimisation for the *HIV Nursing Matters* journal – to be written by the Wits RHI team

## MAJOR PLANS FOR FEBRUARY 2017

### *LOW-DOSE DARUNAVIR STUDY, Wits RHI*

- We hope to complete enrolment by end March 2017
- Start preparing for presenting the first interim analysis of the WRHI052 data to the DSMB in April 2017

### *ADVANCE, Wits RHI*

- The accrual plan for ADVANCE requires that we enrol 20 participants in ADVANCE in February
- Open screening and recruitment at the Shandukani site – this is the site where adolescents, and women who fall pregnant on the study, will be managed

### *MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP*

#### *Country-level activities*

- Disseminate findings from the South Africa needs assessment, and final version of the Impact Overview with the workstream 3 partners
- Initiate interviews for the Mozambique needs assessment, and complete case studies on past transitions
- Continue to engage ICAP's country teams in Cote d'Ivoire, Zimbabwe, Kenya, DRC, and Mozambique in the COP planning process

#### *Collaborations*

- Develop an agenda for the supplier-buyer summit to introduce OPTIMIZE and initiate a discussion with suppliers around multi-month packs and harmonized labeling
- Continue regular conversations with CHAI regarding the coordination of product introduction activities in Kenya
- Attend calls and meetings with WHO, CHAI, and UNITAID to develop enhanced monitoring tools

#### *Early Adopter/Pilot Assessments*

- Develop a concept for an alternative case study around collaborative registration; attend a call with experts on collaborative registration process from Gates and Women Care Global

## NANOTECHNOLOGY, University of Liverpool

- *In vivo* work for DRV/r formulations repeated to further optimise the formulations
- *In vitro* testing and analysis of ATV formulations, including ATV/r formulations

## STAFFING CHANGES

- Congratulations to Jo Livermore, now Jo Sharp, on her nuptials in January! (For now her email address remains the same).
- Our intrepid Research Operations Manager Nkuli Mashabane is going on maternity leave in February – our sadness is only tempered by the return of Project Manager Natasha Arulappan (also from maternity leave).
- ICAP is hiring a Product Introduction Coordinator. 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 – see

[https://www.dropbox.com/home/OPTIMIZETechnicalSteeringCommittee/Calendar+Events](https://www.dropbox.com/home/OPTIMIZE%20TechnicalSteeringCommittee/Calendar+Events))

- None for January.

## MEDIA COVERAGE

- 28 December 2016, The Sowetan: Better, safer, cheaper: the new HIV treatment about to undergo full-scale tests in SA (<http://www.sowetanlive.co.za/news/2016/12/28/better-safer-cheaper-the-new-hiv-treatment-about-to-undergo-full-scale-tests-in-sa>)
- 29 December 2016, Daily Despatch: High hopes for new HIV drug combination (<https://www.pressreader.com/south-africa/daily-dispatch/20161229/281565175425519>)
- 16 January, Wits RHI press release: “ADVANCE Study” – Study launched to test new and safer HIV drugs ([http://www.wrhi.ac.za/uploads/files/160117\\_Wits\\_RHI\\_Press\\_Release\\_ADVANCE.pdf](http://www.wrhi.ac.za/uploads/files/160117_Wits_RHI_Press_Release_ADVANCE.pdf))
- 16 January, USAID web post: New Study Seeks to Accelerate Access to Simpler, Safer and More Affordable HIV Treatment (<https://www.usaid.gov/what-we-do/global-health/hiv-and-aids/resources/news-and-updates/new-study-seeks-accelerate-access>)
- 17 January, Health-e: ADVANCE HIV study set to save SA billions ([www.health-e.org.za/2017/01/17/advance-hiv-study-set-save-sa-billions/](http://www.health-e.org.za/2017/01/17/advance-hiv-study-set-save-sa-billions/))
- 16 January, African News Network: New ARV combo study launched (<http://www.ann7.com/new-arv-combo-study-launched/> 1/) – the same article also published in The New Age (<http://www.thenewage.co.za/new-arv-combo-study-launched/>)