

# Optimising ART

## March 2018



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*This is a monthly update shared with all members involved in projects aimed at optimising ART, 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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Good news this month with the FDA approval of Mylan's fixed-dose combination of DTG, FTC and TAF tablets (50mg/200mg/25mg). This is the smallest size single-tablet regimen available, and will come in either a 30-day or 90-day packaging.

We are also happy to have an update from NAMSAL this month.

The Unitaid Implementers Meeting was held in Geneva, Switzerland from 28 February to 1 March. The purpose of the meeting was to review UNITAID's progress towards the full implementation of their new operating model, which responds to their revised strategy. Implementing partners got the chance to discuss how to improve donor-partner engagement, and learn more about Unitaid's objectives. The presentations from this meeting has been shared with grantees.

### Achievements from February 2018

#### **ADVANCE, Wits RHI**

- Ethics and Medicines Control Council (MCC) approvals were received for Protocol Amendment Version #3.
- 971 participants were enrolled as of the end of February 2018, of which 13 participants are adolescents. The strive to recruit adolescents continues as the team aims for the study to be fully enrolled by end of March 2018, it is more likely that the number of adults recruited will be increased to meet the total recruitment target of 1110 participants as per the protocol.

#### **LOW-DOSE DARUNAVIR (WRHI052), Wits RHI**

- A no cost extension for 6 months has been approved by the MRC, the primary donor for this study.
- Retention rates remain progressively good with the expected participants attending all visits. The last participant last visit is scheduled for May 2018, but the window closes in June.

### Upcoming Events

4-7 Mar: CROI 2018, Boston, USA

8 Mar: OPTIMIZE discussion on external evaluation, New York, USA

### Queries can be directed to:

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

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

- The first patient visit at the Uganda site was on 8 February. Recruitment is ongoing in Uganda, with the first monitoring visit taking place on 23 February.
- Version 8.0 of the protocol is being implemented – this was updated to remove the fasting requirement from some of the visits as a safety measure.
- Soft lock of the database at the UK site has taken place.

### **DTG-RIF TB PK ANALYSIS (RADIO), St. Stephen's AIDS Trust**

- No new activities – ongoing monitoring and data cleaning

### **NAMSAL, Institut de Recherche pour le Développement**

- The last participant was enrolled and randomised on 18 August 2017. Out of a total of 820 subjects screened, 616 were eligible and enrolled in the trial.
- As of 5 March, 589 and 324 participants had reached the week 24 and week 48 visits respectively.
- The Data Safety & Monitoring Board and the Scientific Advisory Board meetings were held on 13 October and 17 November 2017 respectively. At both of these meetings, the treatment adaptation for pregnant women receiving DTG to switch to EFV was discussed. Both boards approved that pregnant women could be maintained on DTG-based treatment, and this protocol amendment was also approved by the ANRS pharmacovigilance department. This amendment was submitted for regulatory approval to the CNERSH in Cameroon (Comité National d’Ethique de la Recherche pour la Santé Humaine) in January 2018.

### **COMMUNITY ENGAGEMENT, TAC**

- Total number of attendees trained for February 2018 was 1488 (note that this excludes the attendees for Gauteng province, as these number were still to be verified)
- Booklet on TLD was completed and the content will be encapsulated into the design of the posters.
- Evaluation forms were designed for both trainers and for trainees. The implementation of such a tool would ensure that there is ongoing assessment of trainings that are conducted, with an opportunity to improve on the trainings conducted and to serve as a transfer of knowledge indicator for those attending the trainings.
- *HIV in our Lives* has been sent for design and layout; the next step is TAC review.

### **Plans for March 2018**

#### **ADVANCE, Wits RHI**

- Planning and finalisation of training for Protocol Amendment Version #3.
- Preparation and QC of data transfer files in preparation for the DSMB in April 2018.

### **LOW-DOSE DARUNAVIR (WRHI052), Wits RHI**

- Address monitoring findings from monitoring visit which was conducted from 12 - 14 February 2018.

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

- Poster to be presented at CROI.
- Planned LPE in Uganda, with last participant last visit by April 2018.
- Close-out monitoring visit at the UK site (including pharmacy).

### **DTG-RIF TB PK ANALYSIS (RADIO), St. Stephen's AIDS Trust**

- Database lock planned for 2 March 2018.
- Close-out monitoring visit planned before mid-March.
- Due to the non-acceptance of the RADIO abstract to CROI, there will be confirmation of details of an alternative submission.

### **NAMSAL, Institut de Recherche pour le Développement**

- Expected approval of amendment #4 submitted to CNERSH regarding use of DTG among pregnant women.
- Next DSMB meeting is scheduled for 15 March.
- Training updated planned for the NAMSAL staff during the second half of March.

### **COMMUNITY ENGAGEMENT, TAC**

- The second draft of HIV in our Lives is expected to be complete by end of March 2018. This draft will incorporate the final design and donor branding and will be circulated for review.
- Training of trainers scheduled for 19 - 23 March 2018.
- Continued planning for the production of the posters on (i) TLD New First Line regimen; (ii) Side effects of DTG; (iii) DTG and pregnancy; and (iv) DTG and TB.

## **Staffing Changes**

- A sad farewell to Dr Firdaus Nabeemeeah, who was a clinician supporting the Yeoville site in ADVANCE. Wits RHI will be recruiting for a replacement clinician.

## **Outputs**

*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>)*

*Also, to assist with all communication, branding and marketing opportunities, please find relevant guidance and documents in the Dropbox at:*

[https://www.dropbox.com/home/OPTIMIZE Technical Steering Committee/Communications+Branding+Marketing](https://www.dropbox.com/home/OPTIMIZE%20TechnicalSteeringCommittee/Communications+Branding+Marketing)

## Papers published

- None

## Talks Given

- None

## Presentations

- CROI 2018, University of Liverpool poster: Preclinical evaluation of a Reduced Dose Darunavir/ritonavir Nanoparticle Formulation. (Can be found on Dropbox: Optimising ART → Calendar + Events → CROI 2018 final poster\_UoL DRV)
- 2018 HIV and Women Conference (Boston, 2-3 March), NAMSAL poster: Contraception among women initiating ARV therapy in the ANRS 12313 NAMSAL trial

## Media Coverage

- 15 February 2018: Association of Schools and Programs of Public Health website: Columbia: ICAP Reports New OPTIMIZE Website Helps Countries Adopt Safe, Simple, Affordable HIV Treatment. <https://www.aspph.org/columbia-icap-reports-new-optimize-website-helps-countries-adopt-safe-simple-affordable-hiv-treatment/>
- 21 February 2018: FDA Tentatively Approves Once-Daily, Fixed-Dose Combination HIV Treatment. <http://www.ajmc.com/newsroom/fda-tentatively-approves-oncedaily-fixed-dose-combination-hiv-treatment>
- 16<sup>th</sup> March 2018: Andrew Owen and Steve Rannard will be interviewed on BBC, Science Friday talking about Nano Medicines.

Other articles/news stories that could be of interest:

- 13 February 2018: Contagion Live. Phase 3 study to assess viral suppression capability of 2-drug ART regimen<sup>1</sup>. <http://www.contagionlive.com/news/phase-3-study-to-assess-viral-suppression-capability-of-2-drug-art-regimen>

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<sup>1</sup> ViiV sponsored TANGO study

## Useful Websites

- USAID page on ART optimisation: <https://www.usaid.gov/what-we-do/global-health/hiv-and-aids/technical-areas/antiretroviral-therapy-optimization>
- UNITAID page on ART optimisation: <https://www.unitaid.eu/project/safer-robust-less-expensive-first-line-antiretroviral-therapy-advance-trial/> (for the grant with Wits RHI, see associated grants below that)
- ICAP website for its OPTIMIZE activities: <https://optimize.icap.columbia.edu/>

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## Future Conferences/Trainings

- 24-27 October 2018: 4<sup>th</sup> Southern African HIV Clinicians Society Conference, Gallagher Convention Centre, Midrand. [www.sahivsoc2018.co.za](http://www.sahivsoc2018.co.za)

## Acknowledgements

The U.S. Agency for International Development (USAID) is a proud supporter of OPTIMIZE. OPTIMIZE is led by the Wits Reproductive Health and HIV Institute (Wits RHI) and founding members include ICAP at Columbia University, Mylan Laboratories, the University of Liverpool, and the UNITAID-funded Medicines Patent Pool. As an expanding partnership aimed at harnessing multiple stakeholders' collective efforts, OPTIMIZE also includes the University of Cape Town (UCT) and contributions from private sector partners. USAID is a key implementing agency of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and is responsible for over half of all PEPFAR programs with activities focused in 35 priority countries and regions, mainly in sub-Saharan Africa and Asia. For more information, please visit: [www.usaid.gov](http://www.usaid.gov)

Unitaid finds new and better ways to prevent, test and treat HIV, tuberculosis and malaria quickly and more affordably. It takes game-changing ideas and turns those into practical solutions that can help accelerate the end of the three diseases. Established in 2006 by Brazil, Chile, France, Norway and the United Kingdom, Unitaid plays an important part in the global effort to defeat HIV, tuberculosis and malaria. For more information, please visit: [www.unitaid.org](http://www.unitaid.org)

