

# Optimising ART

## July 2017



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 by the 1<sup>st</sup> Wednesday of every month.

This month we are happy to have an input from CHAI on their work within the Unitaid-funded OPTIMAL grant.

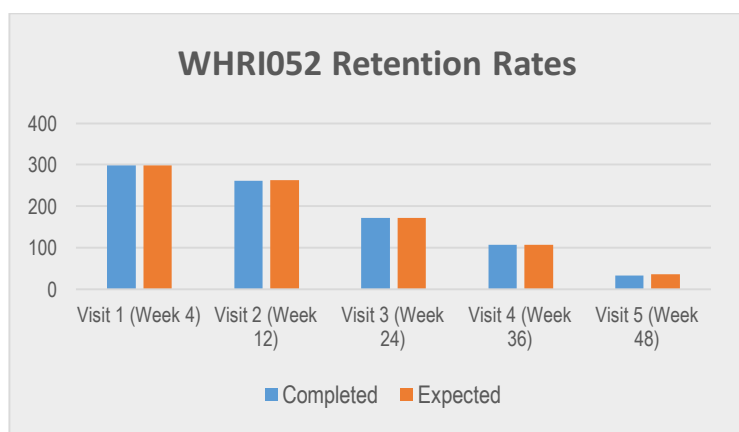
Last week the Department of Health confirmed the plan to extend the current ARV tender to allow for registrations of DTG. See: <https://www.businesslive.co.za/bd/national/2017-06-29-health-department-set-to-extend-aids-drug-tender/>

On more sad news, we say a fond farewell this week to Averie Gachuhi, who is leaving ICAP on 7 July to pursue a career outside of HIV. Averie has been a wonderful collaborator, and she will be missed tremendously. Averie, good luck in this new venture!

## Major Achievements from June 2017

### LOW-DOSE DARUNAVIR STUDY, Wits RHI

- Recruitment is now closed with the last participant enrolled on 15 June. 351 participants were screened in total; 49 screen-failed and 300 enrolled.
- Retention rates have shown tremendous success with average retention of 100% maintained for study visits, as illustrated in the retention graph below.



## Upcoming Events

23-26 July, IAS, Paris, France,  
<http://www.ias2017.org/>

26 July, IAS Satellite: Accelerating Access to DTG and Other Optimal ARVs

27 July, Unitaid Investigators Meeting

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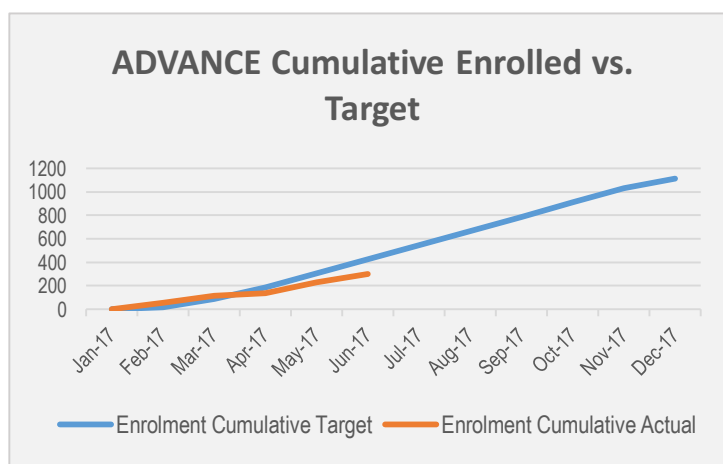
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## ADVANCE STUDY, Wits RHI

- As of 30 Jun, 444 participants were screened, 75 are in the pipeline for eligibility assessment, and 298 enrolled in total.
- To boost recruitment, significant additional human resources are being added in July. In addition, Wits RHI is meeting with other PEPFAR-funded partners working in neighbouring districts to expand the recruitment geographic focus.
- An additional site within Hillbrow, Region F has been submitted for regulatory approval and will serve as a satellite site to provide access to a larger participant pool and hence to accommodate an increase to the rate of participant screening. We expect approval for this site to be granted in July 2017.
- The first two pregnant participants have been successfully transferred to the Shandukani research centre, where they will remain on study and will receive maternal care and follow-up.



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

- SSAT has submitted the IRB submission for study approval in Uganda.
- Recruitment and monitoring activities are ongoing.

## TAF-RIF TB PK STUDY (RIFT), St. Stephen's AIDS Trust<sup>1</sup>

- No further updates since the last activities; 11 participants have been enrolled onto the study.

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

- Submissions have been made to HRA/REC and MHRA.
- The site initiation visit (SIV) is provisionally booked for September.

## NANOTECHNOLOGY, University of Liverpool

- No new updates.

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<sup>1</sup> Funded by Gilead

## MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP

### Country-level activities:

- Mozambique:
  - The needs assessment has been reviewed internally and externally, translated into Portuguese, and graphically formatted. Plans have been initiated to disseminate with the Mozambique MoH and other stakeholders.
- Kenya:
  - DTG was officially launched in Kenya on June 27<sup>th</sup>, 2017 by Unitaid and NASCOP. A communique about the use of DTG was shared with all health facilities. A CME session on DTG use was also hosted by Unitaid a week before the official launch.
  - Kenya has shifted its plan for rolling out DTG so that it will not be at select pilot facilities, but rather will be for 1% of patients nationally. Commodities accounting for 1% of patient populations at facilities were shipped out in June.
  - ICAP met with Palladium, CHAI, and MHealth to discuss national plans for merging various HIS. It was agreed that all organizations will collaborate to develop an interoperable layer to merge the various databases and develop a dashboard that can monitor the uptake of new products.
  - ICAP drafted a series of training materials for healthcare providers on the transition to DTG. These will be reviewed by NASCOP and will be used for training ToT and HCW nationally.
  - As Kenya requires a human subjects waiver for the needs assessment, NASCOP is reviewing the protocol for the situation analysis (needs assessment). ICAP met with NASCOP to review key questions before submission to KEMRI. In the meantime, ICAP has been developing a questionnaire for the situation analysis and developing a list of interviewees with a focus on past transitions including partner roles and responsibilities.
- Zimbabwe:
  - TLE400 has now been delivered to facilities with instructions to be used in adolescent patients and those experiencing side effects with TLE600. Informal discussions with select facilities in Harare has confirmed the arrival of TLE400 and enthusiasm to begin prescribing for patients. The MoH is also deliberating how and when the introduction of TLD should take place.
  - ICAP's Project Officer in Zimbabwe underwent orientation and training on the OPTIMIZE project with the Regional Technical Specialist.
  - ICAP developed a workplan for OPTIMIZE's scope in Zimbabwe to support a baseline analysis for the introduction of TLE400, monitor facility-level uptake, and prepare for the transition to DTG.
  - ICAP completed a draft of the Zimbabwe Needs Assessment, which is currently undergoing internal review.

### Global activities

- ICAP sourced information from ICAP country teams and various stakeholders to elaborate on experiences in past transitions to adult 1<sup>st</sup> line transitions. A first draft of a case study on prior transitions to adult 1<sup>st</sup> line ART is completed and ready to share with USAID for feedback.

- ICAP held a monthly call with CHAI and Wits RHI to discuss current status of projects in Kenya and Zimbabwe, discuss how we can prevent additional procurements of EFV400, share the editorial on EFV400 drafted by USAID, reviewing CHAI's web-based portal, plans for collaboration on webinars and IAS satellite.
- ICAP contributed to a one-pager about DTG introduction by WHO to provide information about Kenya's transition plan.
- ICAP drafted an outline of a product introduction toolkit including checklists for activities for establishing a coordinated mechanism for new product introduction, development, developing new product introduction guidance, developing new product introduction support systems and executing plans for new product introduction.

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

- HIV i-Base continued working on edits for the 2017 editing of *Fit for Purpose* to be distributed at IAS in July 2017.
- HIV i-Base continued working on reviewing and finalising the TAC training materials, including a planning meeting in London.

### COMMUNITY ENGAGEMENT, TAC

- Provincial Train the Trainer (TOT) trainings in all provinces were completed. In addition, TAC will be invited to attend SAHCS provincial seminars as part of continued learning.
- The TOT teams are currently facilitating training at branch levels, which will be ongoing.

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

- The treatment optimisation CME was held in Rustenburg in June, attended by 40 doctors.
- During the SA AIDS Conference (13-15 June 2017) held in Durban, SAHCS organised a treatment optimisation skills building workshop. Despite a snafu in the official conference programme, indicating the wrong session title, around 80 delegates attended the session moderated by Dr Angela Hartwig, Dr Nalini Singh and Prof Motshedisi Sebitloane.
- SAHCS has linked its work on treatment optimisation with that of its Stop Stock Outs project – community advocated now attend the training and presentations on medicines shortages.
- In collaboration with Aurum, SAHCS produced treatment literacy wheels (adult and paediatric) as well as treatment optimisation/literacy board games.
- The Treatment Optimisation learning module of the Advanced HIV Management Course now also includes edited videos from the Cape Town CME session.
- Every Monday SAHCS sends out a Nurses Clinical Tip SMS (text message) to ±2800 nurses.



## **OPTIMAL Project, Clinton Health Access Initiative**

### *IAS 2017 in Paris — Satellite Session: Accelerating Access to Dolutegravir and Other Optimal ARVs*

- CHAI is hosting a satellite session at IAS on Wednesday, July 26<sup>th</sup> from 7am-8:30am.
- The satellite will be chaired by Dr. Yogan Pillay from the National Department of Health, South Africa and will feature speakers from Ministries of Health, WHO, AfroCAB, Unitaid, CHAI, and ICAP. The speakers will present an overview of optimization efforts at global and country levels, with a particular focus on dolutegravir (DTG), and will provide practical steps needed to facilitate and introduce new ARVs in low- and middle-income countries. The agenda for this session is attached at the end of the newsletter.

### *CHAI-UNITAID Optimal ARV Community Advisory Board (CAB)*

- The first meeting of CHAI's Community Advisory Board took place in April in Dakar, Senegal. The meeting brought together representatives from community organizations in each of the UNITAID-CHAI project focal countries to discuss issues related to treatment optimization and to share the latest clinical and market information related to new adult and paediatric products, including DTG.
- In June, the French-speaking CAB representatives from West Africa, including members from Benin, Cameroon, Togo and Senegal met in Yaounde, Cameroon to review clinical and market information and plan treatment optimization activities in the West Africa region.
- In Uganda, meetings were held with members from CHAI's Community Advisory Board and the National Forum for People living with HIV/AIDS in Uganda (NAFOPHANU). The overall goal of the work is to develop a treatment literacy manual to facilitate capacity building for regimen optimization amongst health care workers and to empower patients to hold informed discussions with prescribers on issues related to their treatment plans.

### *Catalytic DTG Procurement*

- To accelerate uptake of DTG and build a market in anticipation of the launch of TLD, in late 2016 CHAI and Unitaid partnered with country governments in Kenya, Nigeria, and Uganda as well as global procurement partners to develop a limited, catalytic procurement initiative.
- CHAI is continuing to support the rollout strategy and transition planning for the catalytic DTG procurement in Kenya, Nigeria, and Uganda. DTG product has arrived in all three countries as of June 2017. DTG was officially launched in Kenya on Wednesday, June 28<sup>th</sup> in an event led by MOH Director of Medical Services and NASCOP.

## **Major Plans for July 2017**

### **Low-Dose Darunavir Study, Wits RHI**

- Finalisation and execution of contract with drug supplier, Hetero India to supply Darunavir 400mg and Ritonavir 100mg, both in tablet formulation.

## ADVANCE, Wits RHI

- Approval for a poster to boost recruitment efforts, which was submitted for regulatory approval at the end of June 2017.
- Extension of recruitment for participants from densely populated, high-burden regions D and E, which neighbour region F; to increase participant reach. Map of local regions within Johannesburg depicted to the right.



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

- Recruitment in the UK (Stage 1 of the study) has been completed. Last participant last visit (LPLV) is anticipated in October 2017.
- Submission to NDA in Uganda for study approval. First participant first visit (FPFV) planned for October 2017.

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

- Preparation for recruitment of participants which is anticipated to start in September 2017.

## MARKET ACCESS AND PRODUCT INTRODUCTION, ICAP

- Mozambique: Hold dissemination meeting for needs assessment and develop initial OPTIMIZE workplan for introduction of optimized ARVs in-country in collaboration with USAID, MOH, and other key stakeholders. Continue to share the most up-to-date evidence and experiences about DTG, including planning a post-IAS update meeting.
- Kenya: Support the finalization of training materials and the TOT training. Develop IEC materials for patients. Continue to plan for the completion of the situation analysis anticipated for August once approved by KEMRI. Collaborate with Palladium to design, develop and pilot an interoperable system that will support enhanced monitoring of ARV products.
- Zimbabwe: Conduct initial baseline analysis of current situation using routinely collected electronic data. Plan to monitor the uptake of TLE 400 in Zimbabwe through site visits and commodity data review meetings at the end of the month.
- Share country needs assessment for external review and finalize with designers. Initiate plans for needs assessment dissemination meeting.
- Global: Continue coordination call with CHAI to discuss webinars, IAS satellite planning, and country-level coordination activities. Disseminate case study on past transitions to partners for review. Share outline of product introduction toolkit with USAID for review. Will also need to coordinate with CHAI's development of "new product introduction portal" to ensure harmonization of messages and avoid duplication. Begin developing webinar for APWG to disseminate supply information on optimized new regimens and post-IAS evidence dissemination.

## COMMUNITY ENGAGEMENT, TAC

- Finalisation and selection of designer/printer for the *HIV in our Lives* hardcopy.

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

- The next CME session is scheduled for 15 July in Durban – and so far, there are 128 RSVPs.
- SAHCS is reviewing staffing levels to increase capacity for the Unitaid-funded work.

## Staffing Changes

- Dr Mhleli Masango has resigned from Wits RHI as of the end of June 2017, and has been replaced by Dr. Masebole Masenya. Wits RHI is currently awaiting regulatory approval for Dr. Masebole Masenya's role as study PI on ADVANCE for Site 03, which focuses exclusively on participants aged 12-18 years, and pregnant women.
- Averie Gachuhi will step down from the Program Manager position on 7 July. Allison Zerbe will take her place, and can be reached at [az2258@cumc.columbia.edu](mailto:az2258@cumc.columbia.edu)

## 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/OPTIMIZE Technical Steering Committee/Calendar+Events](https://www.dropbox.com/home/OPTIMIZE%20TechnicalSteeringCommittee/Calendar+Events))

Also, to assist with all communication, branding and marketing opportunities, please find it 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

Please see the July edition of *Current Opinion in HIV and AIDS* for several articles on ART optimisation (<http://journals.lww.com/co-hivandaids/Pages/currenttoc.aspx#-2071248874>), including those listed below. Unfortunately only two of these articles are available as open access (see highlighted in blue).

- Why a universal antiretroviral regimen? – Charles Flexner, Polly Clayden and Francois Venter
- Antiretroviral dose optimization: the future of efavirenz 400mg dosing – Marta Boffito, Mohammed Lamorde, Melynda Watkins, and Anton Pozniak
- [The ADVANCE study: a groundbreaking trial to evaluate a candidate universal antiretroviral regimen – Francois Venter, Polly Clayden and Celia Serenata](#)
- Compatibility of next-generation first-line antiretrovirals with rifampicin-based anti-tuberculosis therapy in resource limited settings – Gary Maartens, Marta Boffito and Charles Flexner
- Towards a universal antiretroviral regimen: special considerations of pregnancy and breastfeeding – Amy Slogrove, Polly Clayden and Elaine Abrams

- Accelerating access and scale-up of optimized ART in low-income and middle-income countries: a call for a coordinated end-to-end approach – Emily Harris, Carmen Pérez-Casas, Matt Barnhart, Amy Lin, Danielle Ferris Olawale Ajose, Emma Burgess, Rachel Fowler
- When could new antiretrovirals be recommended for national treatment programmes in low-income and middle-income countries: results of a WHO Think Tank – Marco Vitoria, Nathan Ford, Polly Clayden, Anton Pozniak, and Andy Hill

## Media Coverage

- MPP press release about the MOU between MPP and ICAP: <http://www.medicinespatentpool.org/ourwork/tuberculosis/collaborations/>
- Interview with Andrew Owen and Steve Rannard on the future of nanotechnology in HIV: <http://www.thebody.com/content/80121/is-nano-medicine-the-future-of-hiv-treatment.html>
- DTG introduction in Kenya: [https://www.devex.com/news/kenya-becomes-first-country-to-debut-generic-hiv-drug-90563?access\\_key=&utm\\_source=newsletter&utm\\_medium=newswire\\_special&utm\\_campaign=sections&mkt\\_tok=eyJpIjoiTURNeq1qVXhObUk1TkRsaylsluQiOiJYbEJiandBSFhTd0FqRHB2dUJWWkVSckpYWGhUdHBKRUFmeGtiYmV4YjVmTnF0UUyRFZob3lCTVpraWtpVDBCaWVGSm91NE5UZWF2Y2tuSIF0WnpqQ1BhNWNOeis4QUhYOHptS0lyVE1HRVd3eVNYQ09TKzJCNm5MQmt6YlowVyJ9](https://www.devex.com/news/kenya-becomes-first-country-to-debut-generic-hiv-drug-90563?access_key=&utm_source=newsletter&utm_medium=newswire_special&utm_campaign=sections&mkt_tok=eyJpIjoiTURNeq1qVXhObUk1TkRsaylsluQiOiJYbEJiandBSFhTd0FqRHB2dUJWWkVSckpYWGhUdHBKRUFmeGtiYmV4YjVmTnF0UUyRFZob3lCTVpraWtpVDBCaWVGSm91NE5UZWF2Y2tuSIF0WnpqQ1BhNWNOeis4QUhYOHptS0lyVE1HRVd3eVNYQ09TKzJCNm5MQmt6YlowVyJ9)
- Unitaid blog and YouTube video on the introduction of DTG in Kenya: <https://www.unitaid.eu/news-blog/kenya-introduce-better-treatment-people-living-hiv/>
- Guest blog on the HIV Share website by Natalie Martyn of SAHCS on the INTEREST conference: [www.hivsharespace.net/blog/science-and-socialising-interst-2017](http://www.hivsharespace.net/blog/science-and-socialising-interst-2017)

## 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)

## Future Conferences/Trainings

- Rural Health Conference, Taung, 22-25 September 2017: Dr Trevor Majoro confirmed to deliver training on treatment optimisation. [www.rudasa.org.za/conference/about-the-conference](http://www.rudasa.org.za/conference/about-the-conference)
- AWACC, Durban, 7-8 September 2017, [www.awacc.org/2014](http://www.awacc.org/2014) - speakers are being allocated
- 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)



## Accelerating Access to Dolutegravir and Other Optimal ARVs

Wednesday, 26 July 2017

07:00 – 08:30am

IAS 2017, Room 241

*Breakfast will be served*

As the world moves towards meeting 90-90-90 targets there is a need for country programs to rapidly scale up treatment using affordable, safe, and efficacious ARV regimens. This satellite will present an overview of optimization efforts at global and country levels and provide practical steps needed to facilitate and introduce new ARVs in LMIC.

This session will focus on experiences to date with the introduction of dolutegravir (DTG). It will highlight the latest information on the clinical and programmatic implications of new product introduction, market and pipeline updates, and implementation practicalities including national policy change, forecast and tender planning, advocacy and training, service delivery, and enhanced monitoring of new products. It will also review the global activities that enabled the introduction of an affordable product to the market. Country experiences from national programs that are in different stages of introducing DTG will be shared to provide an overview of the practical considerations for the accelerated introduction of simpler, safer, and more affordable HIV treatment.

*(Session chair: Dr. Yogan Pillay, Deputy Director-General: HIV/AIDS, TB and Maternal, Child and Women's Health, National Department of Health)*

### **Welcome and Keynote Remarks**

*Dr. Yogan Pillay*

### **Panel 1: Opportunities, Evidence, and Progress on DTG Development and Commercialization (35 min)**

- 1. The case for introducing optimal ARVs and an overview of global DTG adoption**  
*Carolyn Amole, Senior Director, HIV Access Program, CHAI*
- 2. Clinical considerations of DTG adoption in first-line and how to ensure pediatric treatment isn't left behind**  
*Dr. Nandita Sugandhi, Product Introduction Coordinator, OPTIMIZE, ICAP*
- 3. WHO perspective on DTG**  
*Dr. Marco Vitoria, Medical Officer, HIV Treatment and Care, WHO*
- 4. Panel Discussion: Questions for panel**

**Panel 2: What will it take to scale-up new, optimal first-line regimens? Rapid-fire country experience (40 min)**

- 5. Perspective of the Community: Needs of the PLHIV community and how community can support new product introduction**  
*Kenly Sikwese, Coordinator, AfroCAB*
  
- 6. Experience from adopting countries: Botswana**  
*Dr. Tendani Gaolathe, Botswana Harvard AIDS Institute*
  
- 7. Experience from adopting countries: Kenya**  
*Dr. Maureen Kimani, ART Programme Manager, NASCOP, Kenya*
  
- 8. Experience from adopting countries: South Africa**  
*Gavin Steel, Chief Director, South Africa National Department of Health*
  
- 9. Panel discussion: Panel 2, facilitated by**  
*Robert Matiru, Director of Operations, Unitaid*