

Optimising ART

May 2018



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 1st Wednesday of every month.

The last month has been an extremely busy one for Wits RHI and some of its collaborators. Wits RHI has been working with the South African government to plan for the introduction of TLD into the national programme. This includes participating in the final meeting on the proposed regimens for the ARV tender and the national guidelines. A delay in this introduction will be the regulatory processes, which once again Wits RHI is engaging with the relevant bodies to ensure TLD formulations can be registered in time for the new tender.

Wits RHI also spent significant resources in April preparing for the DSMB meeting in Bethesda, USA, on 30 April. The only study presented to the DSMB is ADVANCE. The formal recommendations are forthcoming, and will be shared with the Scientific Advisory Committee and other relevant stakeholders as soon as it is received. Overall the DSMB is happy with the progress of the trial, and the safety data presented.

Achievements from April 2018

ADVANCE, Wits RHI

- 1041 participants have been enrolled as at 30 April 2018.
- An additional site, Site 04, has been opened from 23 April 2018 to accommodate for further screening and enrolment activities due to the space constraints currently experienced by the other 2 sites. Pooled resources from Sites 01 and 03 have been channelled to Site 04 to ensure that screening and enrolment continues.
- In addition to the focus on ending recruitment, efforts have been contributed towards improving retention and making contact with participants who were considered as “lost to follow-up”.
- ADVANCE was presented to DSMB on 30 April 2018 by Prof FV Venter and Prof Andrew Hill with support from the USAID contingent, Benny Kottiri and Emily Harris.

Upcoming Events

14 May: Scientific Advisory Committee quarterly call

29 May – 1 Jun 2018: 12th INTEREST Workshop, Kigali, Rwanda

JPPM calls have been rescheduled to:

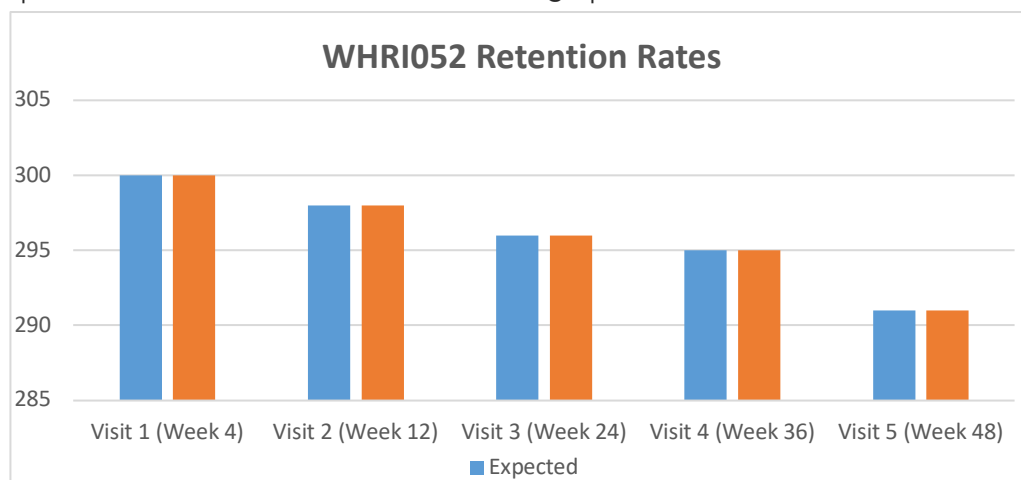
- WS1 on 23 May
- WS2 on 14 May

Queries can be directed to:

Celia Serenata, Wits RHI,
cserenata@wrhi.ac.za

LOW-DOSE DARUNAVIR (WRHI052), Wits RHI

- 100% retention rate has been maintained with 1480 visits successfully completed as at 30 April 2018 as illustrated in retention rates graph.



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

- Final follow-up visits took place and all participants completed the study. Last Patient Last Visit occurred on 13 April 2018.
- A study close-out monitoring visit was conducted at the site in United Kingdom. Only minor investigator-site file actions were pending.

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

- A study close-out visit monitoring was conducted and all pending actions were successfully completed.
- The draft study manuscript was submitted for internal review and feedback to Unitaid and Wits RHI.

NANOTECHNOLOGY, University of Liverpool

- EFV volunteers were administered with their first dose by SSAT as part of the clinical trial of EFV-SDN.
- DRV/r spray was dried in multiple doses *in vivo* for the study planned for early May.
- A contract was signed with Juniper for the manufacture of the DRV/r SDN formulations.

HEALTH WORKER ENGAGEMENT, SAHCS

- Registration for IAS July 2018 has been completed.
- Weekly clinical tips were distributed to 2,325 active members of the Society via SMS.

COMMUNITY ENGAGEMENT, TAC

Training

- Provincial Training of Trainers were held for Limpopo, Mpumalanga, KwaZulu-Natal, Free State, Western Cape and Eastern Cape. TAC community advocates and branch educators were capacitated with information that will be cascaded down to respective branches and communities.
- 1340 people were trained at the provincial branch trainings.

Publications

- *HIV in our Lives* was reviewed and final approved version is currently in print. Plans for distribution of the hardcopies is imminent.

COUNTRY INTRODUCTION & UPTAKE, ICAP

Global Activities

- Hosted a webinar with the APWG on the introduction of optimal new ARVs, and considerations for country programmes. This webinar was 90-minute version of the February webinars geared towards country-level audiences.
- Participated in the annual face-to-face meeting of the APWG.
- Completed a tool on Implementation Considerations for the Introduction of TLD, with an overview of the clinical and programmatic decisions that country programmes should consider when planning for the introduction of TLD, and developing guidance for healthcare workers.

Kenya

- Enhanced Data System (EDS) development:
 - Developed data visualisation dashboards utilising December 2017 data from JOOTRH.
 - Analysed data on AEs from the EDS in JOOTRH to ascertain the functionality of the EDS prior to its scale-up.
 - Supported the installation of the Interoperability Layer (IL) system at Siaya Country Referral Hospital. The IL system is currently undergoing testing to ensure functionality.
- Continued to support NASCOP with the revision of the national ARV guidelines, including ongoing support for the development of an abridged version of the national guidelines.
- Participated in the development of the NASCOP national commodity forecasting and quantification (F&Q) 2018/19 – 2020/21.

Plans for May 2018

ADVANCE, Wits RHI

- Preparation and finalisation of the agenda for the Site Investigator Meeting and Training Workshop scheduled for 06 – 08 June 2018, which will cover all aspects of Protocol Amendment #3.
- Discussions to address and support current retention efforts.

LOW-DOSE DARUNAVIR (WRHI052), Wits RHI

- Complete end of study visits for remaining participants.
- Finalise and submit late breaker abstract to IAS.

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

- PK results are expected following the sample shipment from Uganda to United Kingdom.
- Data to be submitted to IAS as part of a late breaker submission in May 2018.
- Ongoing monitoring and data cleaning activities at the Uganda site.

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

- Conduct study close-out activities.

NANOTECHNOLOGY, University of Liverpool

- SSAT to continue with EFV 2nd stage trial until July.
- Completion and analysis of *in vivo* multiple dose models.
- Juniper project kick-off.

HEALTH WORKER ENGAGEMENT, SAHCS

- Planning and scheduling for attendance and participation at Interest 2018 in Rwanda from 29 May – 1 June 2018.
- Planning for 2-day Optimisation, PrEP and Self-Testing training from 22 – 23 June 2018 in KwaZulu-Natal. This training is partly sponsored by Cipla.
- Optimisation training in Cape Town has been rescheduled to July 2018 and training for Durban is planned for September 2018.
- Planning for viral load training in Polokwane in August 2018 for 150 nurses.

COMMUNITY ENGAGEMENT, TAC

- Training of Trainers for Gauteng scheduled for 02 - 04 May 2018.

- Setup and conduct interviews for a replacement of the Gauteng provincial trainer who resigned in March 2018.

COUNTRY INTRODUCTION & UPTAKE, ICAP

Global Activities

- Finalise the comprehensive training package for healthcare workers to support transition to TLD.
- Finalise the Country Readiness Assessment tool, and make it publicly available through the ICAP/OPTIMIZE website.
- Finalise training modules on pregnancy and toxicity monitoring to support the introduction of TLD.

Kenya:

- Continue providing support to NASCOP towards the revision of the national ARV guidelines.
- Support NASCOP in reviewing DTG uptake data. Discuss gaps identified during the optimisation process with NASCOP to determine strategies to mitigate identified challenges, including addressing the low DTG uptake.
- Provide ongoing technical support to finalise the F&Q report.
- Facilitate a dissemination meeting to share the findings from the Situational Analysis.
- Finalise visualisation dashboards for the EDS.

Staffing Changes

- Welcome to Dr Bronwyn Bosch, a clinician who will be supporting the ADVANCE clinical team at the Yeoville research site.

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/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 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

- None

Resources

- None

Media Coverage

Other articles/news stories that could be of interest:

- Hill A, Clayden P, Thorne C, Christie R, Zash R. Safety and pharmacokinetics of dolutegravir in HIV-positive pregnant women: a systematic review. Journal of Virus Eradication 2018; 4: 66-71. http://viruseradication.com/journal-details/Safety_and_pharmacokinetics_of_dolutegravir_in_HIV-positive_pregnant_women:_a_systematic_review
- 19 April 2018. The Medicines Patent Pool Governance Board appoints Charles Gore as new MPP Executive Director. <https://www.prnewswire.com/news-releases/the-medicines-patent-pool-governance-board-appoints-charles-gore-as-new-mpp-executive-director-680222653.html>

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/>

Future Conferences/Trainings

- 24-27 October 2018: 4th Southern African HIV Clinicians Society Conference, Gallagher Convention Centre, Midrand. 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

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