

OPTIMIZE

This is a monthly update shared with all members of the Project Optimize consortium, and is meant to provide a short update of major achievements, challenges, and plans for the future. Please submit any inputs to Celia Serenata, Averie Gachuhi, and Jo Livermore before the 1st Wednesday of every month.

MAJOR ACHIEVEMENTS FROM MAY 2016

Workstream 0:

- Had a successful Technical Steering Committee meeting in Washington DC
- Set up monthly coordination calls between Wits RHI, ICAP and UoL (first Wednesday of every month). Also reached out to Mylan to determine participation.
- Wits RHI had its first JPPM with Emily in Johannesburg.
- Setting up regular coordination meetings/calls within each of the workstreams is ongoing

Workstream 1:

IS Studies

- Literature review for research capsule completed
- Internal study team assembled
- Research capsule for proposed study drafted, concept presented to consortium

New Formulations

Development of the following products on track:

- TAF/FTC/DTG – Scale-up trial planned in June/July 2016
- TDF/3TC/DTG – BE NOC applied and expected in Q3 2016
- DRV/r/DTG – Formulation trials under progress
- TDF/3TC/EFV 400: Filed with the US FDA in March. Scale-up batches in progress at manufacturing site.



Upcoming Events

June 1

Year 2 workplan template due from USAID

July 12

Year 2 workplan, budget and M&E plan due to USAID

July 18

IAS International AIDS Conference, Durban (18-22 July)

Important Contacts

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Clinical Trials

- Francois Venter attended the NIH DSMB in Washington DC where he presented the ADVANCE study, and the low-dose Darunavir sub-study. Marta Boffito presented the low-dose Efavirenz sub-study. The DSMB had feedback on all studies that may require amendments to the protocols – the formal recommendations have been received and the clinical trials team is working through the responses to the DSMB.

Workstream 2:

- Screening work initiated on drugs sent to UoL by Hetero at the end of April
- Preparation for clinician discussion underway

Workstream 3:

- Business case and stakeholder landscape analysis drafts under review
- Country selection completed; preliminary focus countries are: South Africa, Kenya, Mozambique and Swaziland
- Desk review and phone interviews with consortium members conducted for South Africa country needs assessment
- Coordination with CHAI (Optimal Project) initiated

MAJOR PLANS FOR JUNE 2016

Workstream 0:

- Develop workplans, budgets and M&E plans for Year 2
- Finalize a date for the PAC meeting – likely October or November

Workstream 1:

- Meet with experts to review study capsule and discuss scientific approach (ICAP)
- Attend virtual sensitization with team who developed the adolescent centered care model (ICAP)
- TAF/FTC/DTG – Scale-up trial planned in June/July 2016 (Mylan)
- TDF/3TC/DTF – Bio-equivalence (BE) No Objection Certificate (NOC) applied for and expected in Q3 2016 (Mylan)
- DRV/r/DTF – Pilot BE planned (Mylan)
- Submit the ADVANCE study protocol for Wits Human Research and Ethics Committee approval (Wits RHI)
- Start the low-dose DRV study (pending delivery of the drugs from Hetero) (Wits RHI)

Workstream 2:

- Screening process should continue, and preparation for pharmacology
- Teleconference with clinicians to decide on way forward

Workstream 3:

- Hold meeting with USAID/CII and CHAI to review results from stakeholder landscape analysis and South Africa needs assessment
- Finalize business case for ART optimization and case study on past transition
- Conduct interviews with key players in South Africa for needs assessment once introduced through OHA

STAFFING CHANGES

- ICAP hiring Project Coordinator (technical position for workstream #3):
<http://icap.columbia.edu/jobs/detail/project-coordinator-optimize>
- UoL: Second post-doctoral position advert finished and next stage of process beginning soon

OUTPUTS

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

- None in May. The presentations from INTEREST and the Southern African HIV Clinicians Society conference in April have been uploaded into the Dropbox. (See under OPTIMIZE Technical Steering Committee → 02 – Calendar + Events)