OPTIMIZE

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

Major Achievements from June 2016

LOW-DOSE DARUNAVIR STUDY, Wits RHI

- The study team held a protocol/site initiation training at the Parktonian Hotel from 20-21 June. Around 25 people attended the training, which also provided an opportunity to finalize some of the study SOPs.
- The study drugs (Darunavir 400mg and Ritonavir 100mg tablets) finally arrived on 28 June!

- The team leapt into action, and screened the first patient on 30 June.

ADVANCE, Wits RHI

- Wits RHI submitted the ethics application to the Wits Human Research Ethics Committee (HREC) on 7 June 2016
- A submission was also made to the bio-banking committee on 13 June.
- Wits RHI has started negotiations with Gilead Sciences for the TAF/FTC donation. We are already at the contracting stage, though nothing will commence until MCC and Ethics approval is received. Delivery is expected in late July/early August.

Upcoming Events

July 5

Wits RHI to brief local PEPFAR team on Project OPTIMIZE

July 12

Year 2 workplan, budget and M&E plan for USAID to be finalized

July 18

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

Important Contacts

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- Negotiations for the DTG donation from ViiV Healthcare have commenced, but as they want some minor amendments in the protocol, it may take longer before that donation can be secured.
- A team from UNITAID visited Wits RHI from 28 June to 1 July to work through the UNITAID project document. This will be submitted to the Board by end August 2016.

NANOTECHNOLOGY, University of Liverpool

- The stability testing for the development of darunavir and darunavir/ritonavir solid drug nanoparticles has been completed. The team is now awaiting the radiolabelled versions of these drugs for progression into pharmacology.
- The Project Manager completed the USAID Rules and Regulations course in London, 21-23 June
- The workplan and budgets for Year 2 for USAID have been submitted.

IMPLEMENTATION SCIENCE, ICAP

- A research capsule, including two proposed options, has been refined and formatted to present to experts.
- ICAP attended a virtual sensitization with the team that developed the adolescent-centered care model.
- Had informal conversations with industry around drug supply for implementation science study with adolescents.

DEMAND CREATION AND PRODUCT INTRODUCTION, ICAP

- A call was held with ICAP, Wits RHI, USAID and CHAI to review the stakeholder landscape first draft and preliminary work on the South Africa needs assessment
- ICAP, CII and Wits RHI translated findings from the stakeholder landscape analysis to the Y2 workplan priorities
- Wits RHI, i-Base and ICAP discussed the advocacy strategy; ICAP had follow-up discussions with USAID to determine that Unknown will develop identity strategy and documents and ICAP will outline internal plan for development of various advocacy documents and planned WS3 participation in advocacy for a.
- ICAP engaged with USAID Supply Chain team to discuss the current work on global stock mapping, country-level forecasts, multi-month packs, and harmonization of regimen identifiers
- Impact overview drafted and country-level addendum framework proposed
- Topics for case studies to highlight lessons learned from past ARV transitions proposed and reviewed by ICAP and CII
- Consultant engaged to initiate work on summary of market-shaping materials from past discussions, meetings, and documents
- Hosted Professor Mark Cotton from Stellenbosch University who presented on implications of shift towards birth testing on infant treatment options
- ICAP liaised with the MPP and IMPAACT 2010 study team creating an opportunity to support procurement of generic drug supply

MAJOR PLANS FOR JULY 2016

LOW-DOSE DARUNAVIR STUDY, WITS RHI

- Screen 90 participants by the end of July 2016
- Enroll the first participant in the study by 18 July
- Enter into a contract for an external monitor for the study (Prof. Lesley Burgess)

- Provide training to 2 new staff starting 1 July
- Submit a possible protocol amendment based on the DSMB recommendation

ADVANCE, Wits RHI

- Submission of Dr Joanna Woods as a sub-investigator
- Staff recruitment for several positions: Medical Officers, Pharmacist, Pharmacist Assistant, Research Nurse, and Driver
- Procuring a study vehicle to transport patients between Charlotte Maxeke and the Yeoville Clinic
- Start the open tender process for the CRO, and the drugs to be procured for ADVANCE
- Enter into contracts for the use of the DEXA machine at Charlotte Maxeke, and the laboratory provider
- Finalize the revisions to the protocol to be submitted after approval with key amendments, e.g. the addition of 60 additional children between the ages of 12 and 15; and adding the Shandukani site as a research site (all pediatric patients will be seen there)
- Register the study onto www.clinicialtrial.gov
- Submission to the National Health Research Database (NHRD) and the City of Johannesburg

NANOTECHNOLOGY, University of Liverpool

- Dr. Francois Venter is assisting UoL to set up a conference call with clinicians to determine priority drugs for nanotechnology – this should occur before the end of the month
- Progress work on dolutegravir

IMPLEMENTATION SCIENCE, ICAP

- Share two proposed options for implementation science study with experts
- Finalize the study concept and initiated drafting of the protocol

DEMAND CREATION AND PRODUCT INTRODUCTION, ICAP

- Country introduction emails to be sent to USAID Missions in: Tanzania, Ethiopia, Cameroon, and DRC
- Wits RHI to hold a meeting with PEPFAR SA to introduce project in South Africa; consultant to plan travel to SA to conduct needs assessment, if appropriate, and continue desk review
- Expanded consortium to review stakeholder landscape analysis by section
- ICAP to produce summary of market-shaping materials to share with expanded WS3
- ICAP to develop and share internal advocacy strategy listing advocacy documents and fora for discussion in Y2
- Consortium partners will collaborate with ICAP to conduct data collection for country-specific information relevant to priority case studies
- ICAP, CII, and MPP to discuss refinements for country addendum to impact overview; overarching impact overview to be finalized
- ICAP and MPP to continue conversation on supply-chain related activities proposed for Y2

Staffing Changes

- Wits RHI: Two data capturers to work on the DRV study started on 1 July
- UoL: Recruitment of second post-doctoral research associate to be completed by the end of July. This will complete the staff for the University of Liverpool.
- ICAP: Conducted interviews for the Project Coordinator position

Outputs

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

- None.