Project Brief: HPTN 084-01

Full Title of Study/Programme	HPTN 084-01: Safety, Tolerability and Acceptability of Long-Acting Cabotegravir (CAB LA) for the Prevention of HIV among Adolescent Females – A Sub-study of HPTN 084
Technical Focus Area/Key Words	HIV Prevention , Long acting Injectable, Cabotegravir (CAB LA)
Rationale	Despite reductions in other age groups, the number of deaths attributable to HIV is rising in the adolescent age group. As with many daily medication regimens, the effectiveness of oral PrEP is highly dependent on adherence to the prescribed drugs. This appears to be particularly true for adolescents and young adults. Adult safety data on long-acting cabotegravir (CAB LA) will need to be expanded to adolescents in order to license the product for adolescents under the age of 18.
Primary Objectives	To evaluate the safety, tolerability and acceptability of CAB LA in healthy, HIV-uninfected female adolescents aged below 18 years.
Secondary Objectives	To examine adherence to and timeliness of injections over time among adolescent participants provided CAB LA and information regarding its safety and unknown efficacy. To examine patterns of sexual risk behaviour over time among adolescent participants provided CAB LA and information regarding its safety and unknown efficacy. To evaluate the safety of CAB LA for 48 weeks of follow-up after final injection.
Primary Endpoint/Outcome	Safety endpoint: Proportion of participants experiencing any Grade 2 or higher clinical adverse events (AEs) and laboratory abnormalities among participants who receive at least one injection of CAB LA Tolerability endpoint: Proportion of participants who receive at least 1 injection and who discontinue receiving injections prior to the full course of injections due to intolerability of injection, frequency of injections or burden of study procedures Acceptability endpoints: Proportion of participants who complete all scheduled injections and proportion of participants who receive at least one injection who would consider using CAB LA for HIV prevention in the future
Secondary Endpoint/Outcome	Grade 3 or higher clinical and laboratory AEs
Study Design	This is a single arm, open label, safety, tolerability, and acceptability study of CAB LA for prevention of HIV-acquisition in sexually-active, HIV-uninfected adolescents (<18 years old at time of enrollment).
Study arms	Single arm CAB LA
Study population	Sexually-active, HIV-uninfected adolescents (<18 years old at time of enrollment)
Study sample size	Approximately 50 participants
Follow up/duration	Approximately 87 weeks, or approximately 1.5 years.

Study/Programme sites	Ward 21 CRS, Johannesburg, South Africa Spilhaus CRS, Harare Zimbabwe MU-JHU Research Collaboration (MUJHU CARE LTD) CRS, Kampala, Uganda
Study/Programme duration	Participant recruitment will take approximately 12 months. Oral study product will be administered for 5 weeks, followed by 34 weeks on injectable product then quarterly visits for 48 weeks after final injection.
Intervention	CAB (oral and LA injectable)
Investigators	IOR: Prof Sinead Delany-Moretlwe Sub Investigators: Dr Carrie-Anne Mathew, Dr Elizabeth Roos, Dr Kim Helen Comline
Other Partners & Collaborators	ViiV Healthcare.
Sponsors/Donors	Division of AIDS (DAIDS), United States (US) National Institute of Allergy and Infectious Diseases (NIAID), Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), US National Institutes of Health (NIH).
Linked Parent Protocol and post grad projects	HPTN 084: A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Publications/key presentations to date	None
Progress Update as at 08 March 2021	Screened: 5 Enrolled: 2
Frequency of donor narrative report	Annual
Overall Study/Project Contact	Dr Carrie- Anne Mathew cmathew@wrhi.ac.za 0822596969
Briefing owner and date	Dr Carrie- Anne Mathew cmathew@wrhi.ac.za 08 March 2021