AVAC
Global Advocacy for HIV Prevention

Status Updates on Ongoing and Planned HIV Px Trials as of April 22, 2020

The world is grappling with the far-reaching impacts of the COVID-19 pandemic and the HIV prevention field is no different. Most trials investigating new biomedical HIV prevention products have paused, citing concerns for the safety of trial participants and the study teams. How COVID-19 is impacting research varies by trial and site, and efforts are ongoing to minimize impact on trial timelines and data. AVAC will continue to monitor developments—watch this space: https://www.avac.org/resource/status-updates-ongoing-and-planned-hiv-prevention-trials.

Study Number/Description	Countries	Status update
Phase I		
HPTN 083-01 Safety, tolerability and acceptability of long-acting cabotegravir (CAB LA) among adolescent males	US	Screening and enrollment paused
HPTN 084-01 Safety, tolerability and acceptability of long-acting cabotegravir (CAB LA) among adolescent females	South Africa, Uganda, Zimbabwe	Screening and enrollment paused
HVTN 127/ HPTN 087 Safety, tolerability, and serum concentrations of a VRC07-523LS human monoclonal antibody	US, Switzerland	All infusions complete; visit windows will be flexible, and will follow institutional policy
HVTN 130/HPTN 089 Safety, tolerability, pharmacokinetics, and antiviral activity of combinations of monoclonal antibodies	US	All infusions complete; sites adhering to institutional policy for any follow-up
HVTN 136/HPTN 092 Safety, tolerability, pharmacokinetics, and antiviral activity of monoclonal antibody PGT121.414.LS alone and with VRC07-523LS	US	Screening and enrollment paused
MTN-039 Safety and pharmacokinetic study of rectal administration of a tenofovir alafenamide/elvitegravir insert	US	Screening and enrollment paused
Phase II/III		
HPTN 083 Safety and efficacy study of injectable cabotegravir compared to daily oral tenofovir disoproxil fumarate/emtricitabine (TDF/FTC)	Argentina, Brazil, Peru, South Africa, Thailand, US, Vietnam	Screening and enrollment paused at the small subset of non-US sites participating in the expanded enrollment
HPTN 084 Safety and efficacy of the long-acting injectable agent cabotegravir (CAB LA) compared to daily oral tenofovir disoproxil fumarate/emtricitabine	Botswana, Kenya, Malawi, South Africa, Swaziland, Uganda,	Screening and enrollment paused in S. Africa and Eswatini; follow-up visit guidance provided by study leadership

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(TDF/FTC)	Zimbabwe	
HVTN 804/HPTN 095 Antiretroviral analytical treatment interruption (ATI) to assess responses in participants who became HIV-infected during HVTN 704/HPTN 085	Brazil, Peru, Switzerland, US	Screening and enrollment paused
HVTN 703/HPTN 081 Safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection	Botswana, Kenya, Malawi, Mozambique, South Africa, United Republic of Tanzania	All further infusions discontinued; participant follow-up continues, utilizing remote or in-person visits as feasible.
HVTN 704/HPTN 085 Safety and efficacy of the human monoclonal antibody (mAb) VRC-HIVMAB060-00-AB (VRC01)	Brazil, Peru, Switzerland, US	All further infusions discontinued; participant follow-up continues, utilizing remote or in-person visits as feasible.
HVTN 705/HPX2008 (Imbokodo) Vaccine regimen based on mosaic immunogens designed to offer protection against a variety of global HIV strains	South Africa, Malawi, Mozambique, Zambia, and Zimbabwe	Guidance tailored to the particular circumstances of participating countries and study sites; may also involve temporarily pausing vaccinations
HVTN 706/HPX3002 (Mosaico) Mosaic- based vaccine regimen tested in men who have sex with men (MSM) and transgender individuals	Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain and the United States	Temporarily paused all new screening, enrollment, and vaccination visits through May 1, 2020; pause to be reassessed periodically
HVTN 702 (Uhambo) ALVAC/protein prime-boost vaccine regimen; trial stopped vaccinations in February 2020 for non-efficacy	South Africa	Each participating site to implement measures aligned to guidance from local public health authorities and Ethics Committee; includes expanding visit windows, delaying visits and/or conducting some visit procedures remotely
MK-8591/Islatravir Evaluate the safety, tolerability, and pharmacokinetics of oral MK-8591 once-monthly in participants at low- risk for HIV-1 infection	US, Israel, South Africa	Enrollment paused; those already enrolled will continue with study visits
MTN-034 (REACH) Safety of and adherence to the Dapivirine vaginal ring and oral emtricitabine/tenofovir disoproxil fumarate	South Africa, Uganda, Zimbabwe	Screening and enrollment paused; follow-up with current participants as feasible
MTN-042 (DELIVER) Randomized, open label safety trial of dapivirine vaginal ring (VR) and oral Truvada use in pregnancy	Malawi, Uganda, South Africa, Zimbabwe	Screening and enrollment paused, but site activation is ongoing; follow-up for current participants to continue as feasible with guidance from protocol leadership
PrEPVacc	Mozambique,	Registration cohort paused; trial start to be

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Three-arm, two-stage HIV prophylactic vaccine trial with a second randomization to compare TAF/FTC to TDF/FTC	South Africa, Tanzania, Uganda	evaluated in June. For more information click here
Observational Studies		
HPTN 083-02 Factors influencing adherence to injectable PrEP and retention in an injectable PrEP research study	Brazil, South Africa, US, Thailand	Screening and enrollment paused
MTN-042B Assessing baseline pregnancy outcomes in Sub- Saharan Africa	Malawi, Uganda, South Africa, Zimbabwe	Study closeout
MTN-045 Dual Purpose Prevention (DPP) product preferences among couples	Uganda and Zimbabwe	Study paused
Open-Label Study		
MTN-035 (DESIRE) Acceptability, tolerability, and adherence of three rectal microbicide placebo formulations	Malawi, Peru, South Africa, Thailand, US	Screening and enrollment closed; Follow-up with current participants as feasible