

Public statement by the HIV Vaccine Trials Network (HVTN) on COVID-19

April 1, 2020

We acknowledge and thank all members of our communities and organizations who are at the forefront helping in the response to overcome COVID-19. We laud your service and unwavering commitment!

The HVTN continues to monitor the impact of COVID-19 on the conduct of the early and large-scale clinical trials we coordinate globally. We remain committed to the safety and wellbeing of all study participants and study teams.

In a previous [statement](#), we outlined how our study teams are empowered to implement measures necessary to prevent the possible transmission of COVID-19 at each trial site. All measures are aligned with the recommendations and guidance from local public health authorities and Institutional Review Boards/Ethics Committees. In addition, some trial sites abide by specific requirements of their larger research organization or health care facility.

The impact of COVID-19 is evolving rapidly and many countries are introducing response measures such as school and business closures and asking people to stay home. All measures aim to stop transmission and save lives.

An update on the status of the large-scale clinical trials coordinated by the HVTN is provided in the accompanying table: **Impact of COVID-19 on large-scale antibody-mediated HIV prevention efficacy clinical trials and HIV vaccine efficacy trials**

As a general approach, all trial sites are implementing the following measures to stop the transmission of COVID-19:

- Schedule telephone or virtual study participant visits
- Require those with a scheduled appointment to contact the site beforehand if they feel unwell
- Encourage physical distancing to minimize potential exposures in the waiting area or while visits are being conducted
- Monitor the temperatures of the clinic staff and participants upon entering the clinic
- Frequently clean and disinfect all surfaces
- Frequently hand wash with soap for at least for 20 seconds.

Our mission remains the pursuit of a safe and globally effective preventive HIV vaccine to help end HIV. We appreciate the collaborative efforts at all sites to ensure the safety of participants and staff and preserve the scientific integrity of each clinical trial.

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Impact of COVID-19 on large-scale antibody-mediated HIV prevention efficacy trials and HIV vaccine efficacy trials

Study Number/Description	Current status	What has changed	Countries
<p>HVTN 703/HPTN 081 HVTN 704/HPTN 085 (Antibody Mediated Prevention studies [AMP])</p> <p>AMP is testing whether a broadly neutralizing antibody called VRC01 can prevent HIV acquisition in people.</p>	Fully enrolled	The leadership of the AMP studies has discontinued all further infusions in the interest of staff and participant safety. The data accrued on infusions already administered are sufficient to achieve the study objectives. Participant follow-up continues, utilizing remote or in-person visits as feasible.	Two studies are underway in 11 countries: Botswana, Brazil, Kenya, Malawi, Mozambique, Peru, South Africa, Switzerland, Tanzania, the United States and Zimbabwe
<p>HVTN 705/HPX2008 (Imbokodo)</p> <p>Imbokodo is testing an investigational vaccine regimen based on mosaic immunogens – vaccine components comprising elements from multiple HIV variants – designed to offer protection against a variety of global HIV strains. The study has enrolled women aged 18-35 with the goal of determining if the vaccine regimen is effective in preventing HIV infection.</p>	Fully enrolled	To ensure the health and safety of study participants and staff, the leadership of the Imbokodo study has issued guidance that is specific to the particular circumstances of participating countries and study sites. Where appropriate, this guidance may include temporarily pausing vaccinations.	South Africa, Malawi, Mozambique, Zambia, and Zimbabwe
<p>HVTN 706/HPX3002 (Mosaico)</p> <p>Mosaico is testing an investigational mosaic-based vaccine regimen that is very similar to the regimen being studied in Imbokodo, with the goal of determining if it is effective in preventing HIV infection in men who have sex with men (MSM) and transgender individuals aged 18-60.</p>	Enrollment paused	To ensure the health and safety of study participants and staff, the leadership of the Mosaico study has temporarily paused all new screening, enrollment, and vaccination visits through May 1, 2020. The pause will be reassessed periodically to determine next steps.	Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain and the United States
<p>HVTN 702 (Uhambo)</p> <p>Uhambo tested an experimental vaccine regimen against HIV that builds on the regimen tested in the RV144 clinical trial conducted in Thailand.</p>	Vaccinations stopped in February 2020, but participant follow-up continues	The leadership of the Uhambo study has empowered each participating site to implement measures aligned to guidance from local public health authorities and Ethics Committees. This includes expanding visit windows, delaying visits and/or conducting some visit procedures remotely.	South Africa