

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	Vaccinations in Imbokodo are nearing completion. 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 while vaccinations are completed. Janssen and its partners will continue to closely monitor the COVID-19 situation.	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 ongoing	To ensure the health and safety of study participants and staff, the leadership of the Mosaico study team has developed a specific process allowing activity to resume on a site-by-site basis when deemed safe to do so based on a risk assessment and approval for each location. Previously there had been a hold on certain clinical trial activities (such as screening and new enrollments) until June 1st 2020. As the pandemic evolves, this delay has now been lifted. Janssen and its partners will continue to closely monitor the COVID-19 situation.	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