## **AVAC** The Years Ahead in Biomedical HIV Prevention Research Status of select biomedical HIV prevention clinical trials Global Advocacy for HIV Prevention **Efficacy Trial** 2021 2022 2024 2019 2020 2023 **Vaginal Ring** Jan 2021: WHO recommends as an additional prevention choice for women at substantial risk of HIV. Jul 2020: **Dapivirine Ring (Monthly)** Approved in multiple African countries and under review by a number of additional regulatory authorities. European Medicines Agency issues a positive **Dapivirine Ring** opinion **IPM 054** (Every three Bioequivalency trial of 3-monthly DVR among 110 Women in South Africa months) **Oral PrEP** Oct 2019: FDA approves F/TAF for adults and adolescents who have no HIV risk from receptive vaginal sex **DISCOVER F/TAF** 2016-2027: Randomized controlled trial of daily F/TAF in men and transgender women who have sex with men (Daily pill) **PURPOSE 1** 2021-2027: Trial of six-monthly injectable lenacapavir planned in 5,010 AGYW in South Africa, Uganda alongside daily oral F/TAF. Randomized controlled trial of monthly islatravir; ongoing in 4,500 women in the US **IMPOWER-22** Islatravir September 2022: Discontinued (Monthly pill) Randomized controlled trial of monthly islatravir in men and trangender women who have sex with men across the world **IMPOWER-24** September 2022: Discontinued **Long-Acting** Randomized controlled trial of injectable cabotegravir every two months; ongoing in 4,500 MSM and transgender Iniectable **HPTN 083** Dec 2021: FDA approves CAB-LA for PrEP in the US. Multiple women in Argentina, Brazil, Peru, South Africa, Thailand, US, Vietnam applications under review with other regulatory bodies. Cabotegravir **HPTN 084** (Every two months) Randomized controlled trial of injectable cabotegravir every two months; ongoing in 3,200 women in Botswana, Kenya, Malawi, South Africa, Uganda, Zimbabwe **PURPOSE 1** 2021-2027: Trial of six-monthly injectable lenacapavir planned in 5,010 AGYW in South Africa, Uganda alongside daily oral F/TAF. Lenacapavir (Every six months) **PURPOSE 2** 2021-2027: Trial of six-monthly injectable lenacapavir in 3,000 cisgender MSM, transgender women, transgender men, and gender non-binary individuals. **Preventive HIV Vaccine** Randomized controlled trial of ALVAC/gp120 prime-boost with MF59 adjuvant, six doses over 18 months; 5,400 men and women in South Africa; ALVAC/gp120 **HVTN 702** immunizations halted for non-efficacy; follow-up ongoing w/MF59 August 2021: The vaccine was safe, but did not significantly reduce the risk of HIV. Imbokodo (HVTN Ad26/gp140 705/ HPX2008) boost Randomized controlled trial of Ad26 prime with gp140 boost; four doses over 12 months; fully enrolled 2,600 women in Malawi, Mozambique, South Africa, Zambia, Zimbabwe Ad26/clade C Jan 2023: The vaccine was safe, but was not effective Mosaico (HVTN 706/ gp140 & mosaic HPX3002) at preventing the acquisition of HIV. Randomized controlled trial of Ad26 prime with clade C and mosaic gp140 boost; ongoing in 3,800 MSM and transgender gp140 boost people in Argentina, Brazil, Italy, Mexico, Peru, Poland, Spain, US **Oral PrEP PrEPVacc** and vaccine Randomized controlled trial of DNA-MVA-env or DNA-env with F/TAF or F/TDF; planned in 1668 participants in Mozambique, South Africa, Tanzania, Uganda **AMP (HVTN 704/** Randomized controlled trial of the VRCQ1 antibody infused every two months; ongoing in 2,700 MSM and transgender men & women in Brazil, Peru, Switzerland, US

Jan 2021: VRC01 did not significantly reduce the overall risk of HIV acquisition, but it reduced risk from HIV strains

classified as highly-sensitive to VRC01.

Randomized controlled trial of the VRCO1 antibody infused every two months; ongoing in 1,900 women in Botswana, Kenya, Malawi, Mozambique, Tanzania, South Africa, Zimbabwe

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**HPTN 085**)

**HPTN 081**)

**AMP (HVTN 703/**