CAPRISA
CENTRE FOR THE AIDS PROGRAMME OF RESEARCH IN SOUTH AFRICA

Newsletter

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First human trial of long-acting TAF implant for HIV prevention completed

The first-in-human trial of a long-acting tenofovir alafenamide (TAF) implant for HIV prevention was conducted in Durban, South Africa. The CAPRISA 018 Phase I study tested the safety, tolerability, and pharmacokinetics of a subdermal TAF reservoir implant designed to deliver protection for up to a year. This is a critical step in efforts to develop discreet, long-acting prevention options for women in sub-Saharan Africa, where HIV risk remains high.

Thirty-six HIV-negative women aged 18–40 were enrolled between July 2020 and May 2022. Participants received either one or two TAF implants or placebo, with follow-up for 48 weeks. Systemic adverse events were similar between groups, but local implant site reactions (ISRs)—including scarring, induration, and hyperpigmentation—were common in the TAF group. About 36% of participants opted for early removal, with a median removal time of 19 weeks.

The implant released approximately 0.1mg of TAF per day, below the targeted 0.25mg/day, and intracellular drug levels did not consistently achieve protective thresholds. Despite no severe skin reactions (unlike prior animal studies), tolerability concerns and insufficient drug release halted further development of this implant.

This trial provided important insights into the challenges of implantable antiretrovirals. Further research is needed to understand ISR mechanisms and to design implants that optimize both tolerability and efficacy. While this candidate will not proceed, the study advances the field towards viable long-acting HIV prevention solutions for women.

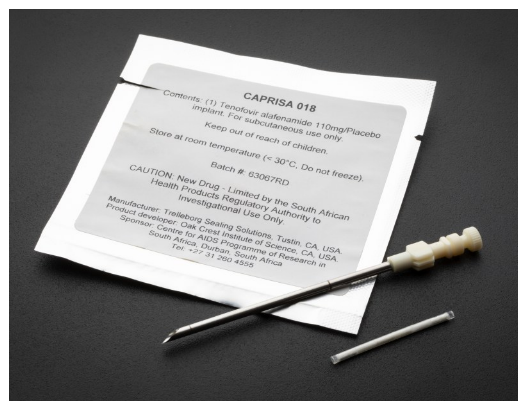

Photo: TAF implant and trocar used in the CAPRISA 018 Phase I trial

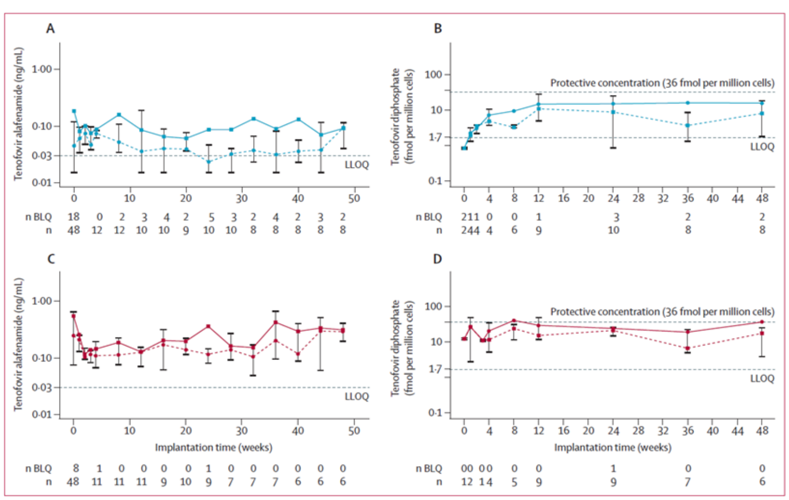

Figure 3: Tenofovir alafenamide plasma concentrations and tenofovir diphosphate peripheral blood mononuclear cells concentrations in group 2
Mean or median values per timepoint are indicated with solid or dashed blue and red lines. (A and B) Participants with one implant. (C and D) Participants with two implants. BLQ=below the limit of quantitation. LLOQ=lower limit of quantitation.

For further reading: Gengiah TN, Lewis L, Harkoo I, et al. Safety, tolerability, and pharmacokinetics of an annual tenofovir alafenamide silicone subdermal implant in South African women: a two-part, randomised, placebo-controlled, double-blind, first-in-human, phase 1 trial. *Lancet HIV* 2025. https://doi.org/10.1016/S2352-3018(25)00079-7

In this Issue

On Page 1, Senior Scientist Tanuja Gengiah shares the results of the CAPRISA 018 Phase I study that studies long-acting TAF in HIV prevention.

On Page 2, The Virchow Foundation recognises the contribution to HIV prevention by Professor Quarraisha Abdool Karim.

On Page 3, Team CAPRISA shines at IAS 2025.

On Page 4, Vaccine research warmly received by China CDC.

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Virchow Prize 2025: Recognition for leadership in HIV prevention in women

CAPRISA Associate Scientific Director Professor Quarraisha Abdool Karim has been awarded the Virchow Prize 2025 for pioneering lifelong leadership in advancing maternal, newborn and child health equity through community-centred, evidence-based research.

German physician and anthropologist Rudolf Virchow is best known for his theory of cellular pathology that shaped the understanding of disease by emphasizing the role of cells as the fundamental units of life and disease. Virchow was also a prominent public health advocate and social reformer, recognizing the connection between social conditions and health.

In this vein and in accepting this latest honour, Abdool Karim spoke to one of the key findings of her working, notably, the disproportionate burden of HIV infection in women compared to men in South Africa and the earlier age of HIV acquisition in young women compared to their male peers. She said "Further investigation of this age-sex difference through socio-epidemiological studies of women in various settings in South Africa highlighted the prevention gap and set me on the quest to find a woman-initiated technology as a first step to address the underlying root cause of gender-power disparity.

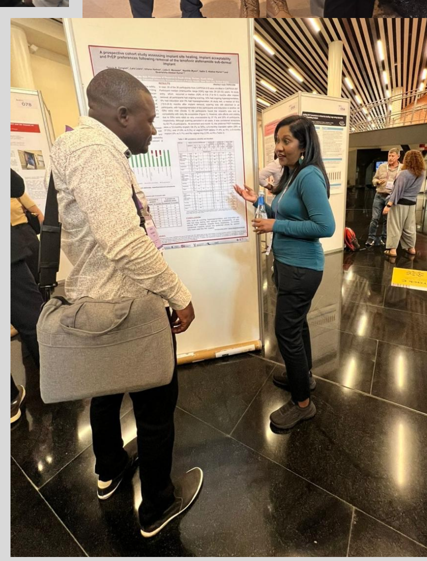
In a statement, the Foundation said, "The Virchow Prize 2025 laureates have shaped health policies and practice by closing critical gaps in care for vulnerable populations. Their leadership has ensured that life-saving services reach those in low-resource and crisis-affected settings, where health systems are often weakest and disparities most acute. Abdool Karim shares this honour with fellow laureate, paediatrician and epidemiologist, Zulfiqar A. Bhutta. Dr. Bhutta has championed community-based primary care models, large-scale randomised trials, and implementation research within vulnerable communities. He is the Founding Director of the Institute for Global Health and Development at Aga Khan University in Karachi, Pakistan and Co-Director of the SickKids Centre for Global Child Health.

IAS 2025 places Africa at the centre of shaping the global HIV response

Several senior CAPRISA scientists and researchers participated in the IAS Conference on HIV Science in Kigali in Rwanda this month. The meeting of the International Aids Society places the global HIV response under the spotlight bringing together scientific advances, global policy and activism. Among the major themes that emerged at this year's meeting and highlighted by the IAS includes, the impact of the funding cuts by the United States, the central role of African science in shaping the global HIV response , WHO recommended Lenacapavir (LEN) for HIV prevention in new guidelines, the growing toolbox of long-acting options and bNab breakthroughs.

Last month, the FDA approved injectable Lenacapavir for HIV prevention. This came on the back of promising results from the PURPOSE1 and PURPOSE2 trials which demonstrated the safety and efficacy of Lenacapavir across diverse populations and settings. According to the World Health Organisation, Lenacapavir's discreet, long-acting formulation may help overcome key barriers such as daily pill burden, frequent clinic visits, and stigma associated with HIV prevention.

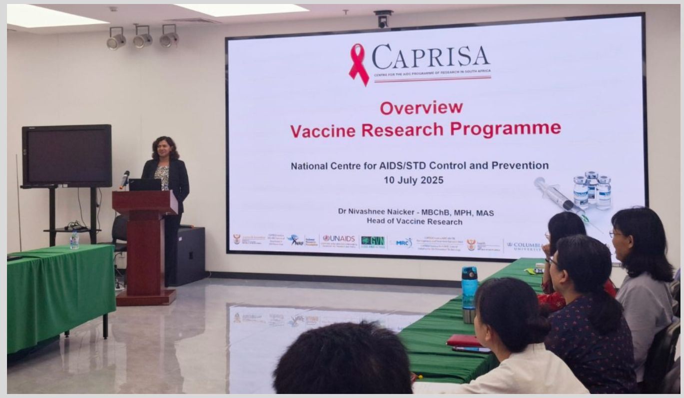
According to the IAS, while delegates welcomed bipartisan moves by the US Senate to protect the US President's Emergency Plan for AIDS Relief (PEPFAR) from USD 400 million in federal funding cuts, the impact continues to be severe.



Photos: (Top, left: IAS 2025 opening ceremony. Top, right: ECRS and VCRS teams at the EXPrESSIVE meeting. Bottom, left: Research fellows, Thando Maseko and Kwena Thlaku. Bottom, middle: Senior scientist and CAPRISA Head of Pharmacy Tanuja Gengiah, Bottom, right: Senior scientist Leila Mansoor

HIV vaccine research crosses borders

Dr Nivashnee Naicker - Head of Vaccine Research - visited the National Centre for AIDS/STD Control and Prevention of the China Centre for Disease Control.



The centre is led by distinguished Professor Yiming Shao, China CDC's Chief Expert on AIDS. Professor Shao and his team are actively involved in advancing research in HIV vaccines and in bNAb development.

Speaking to her visit, Dr Naicker said she was encouraged by the active interest demonstrated by senior scientists at the centre, in the work being undertaken at CAPRISA, and the shared passion for pursuing a successful HIV vaccine candidate. Dr. Naicker said, “This sets the stage for us to fruitfully engage in collaborative opportunities going forward.”

CAPRISA opens its doors to young learners

A group of Grade 11 and 12 learners spent time across different departments in CAPRISA as part of the Young Adults Workplace Experience Programme. The annual initiative is designed to guide learners in making confident careers decisions by providing them with valuable insights for their future.

Learners had the opportunity to explore study options that align with their aspirations, engage with professionals in various fields, and gain hands-on experience. This immersive experience not only broadened their understanding of potential career paths but also inspired them to pursue their goals with greater clarity and determination.

Photo: Participants in the Young Adult Work Experience Programme with Head of HR Naren Dhoodhanath, Sma Mzobe Training co-ordinator and Thobile Thusi HR administrator.

A selection of scientific papers published in 2025

98 **Abdool Karim S**, Kruger P, Erzse A, Rwafa-Ponela T, Nyatela A, Lalla-Edward S. The impact of Covid-19 on food aid systems in South Africa: a cross-sectional mixed-methods study. Health Promot Int. 2025 May 13;40(3):daaf070. doi: 10.1093/heapro/daaf070.

99 Huang Y, Zhang L, Gelderblom H, Seaton KE, Yates NL, Paez CA, Karuna ST, Andrew P, Gamble T, Robinson ST, Ledgerwood JE, Hyrien O, Walsh SR, Gay CL, Gwira JA, Spiegel HML, Sobieszczyk ME, Mannheimer SB, Edupuganti S, Hurt CB, Stephenson KE, Yu C, Kelley CF, **Mahomed S**, Siegel M, Yacovone M, Pensiero MN, Donnell D, Cohen MS, Corey L, Gilbert PB, Koup RA, Tomaras GD; VRC 605, HVTN 127/HPTN 087, HVTN 130/HPTN 089, HVTN 136/HPTN 092, and HVTN 140/HPTN 101 study teams. Fixed dosing versus weight-based dosing of HIV-1 prophylactic monoclonal antibodies in adults: a post-hoc, cross-protocol pharmacokinetics modelling study. EBioMedicine. 2025 Jun 13;117:105804. doi: 10.1016/j.ebiom.2025.105804.

100 Ndlovu B, Gounder K, Zikhali N, Singh L, Ntshangase N, Gumede N, Millar J, van Dorsten RT, Grayson NE, Bonsall D, Chaudron SE, Mabuka J, Dong KL, Walker BD, **Moore PL**, Goulder PJR, Ndung'u T. Distinct neutralization sensitivity between adult and infant transmitted/founder HIV-1 subtype C viruses to broadly neutralizing monoclonal antibodies. PLoS Pathog. 2025 Jun 23;21(6):e1013245. doi: 10.1371/journal.ppat.1013245.

101 Maueia C, Murahwa AT, Carulei O, **Taku O**, Mbulawa Z, Manjate A, Valey ZO, Mussá T, Williamson AL. Genetic variability in HPV 33 and 35 E6 and E7 genes from South African and Mozambican women with different cervical cytology status. Virol J. 2025 Jul 10;22(1):234. doi: 10.1186/s12985-025-02851-2.

102 Sutar J, Jayal P, Mullick R, Chaudhary S, Kamble P, Bhowmick S, Kaginkar S, Padwal V, Devadiga P, Neman N, Kitchin D, Kaldine H, Mkhize NN, Ndlovu B, Gounder K, Mukherjee S, Shrivas S, Sharma N, Prasad C, Tewatia S, Parihar N, Kumar N, Kasarpalkar N, Singh B, Mohapatra S, Aquil M, Kumar CV, Dinesha TR, Srikrishnan AK, Shastri J, Agrawal S, Gaikwad S, Mondal S, Bandyopadhyay B, Guha SK, Kale D, Biswas D, Patil D, Paranjape RS, Mukhopadhyay S, Hema, Das R, Kondapi A, Bhor V, Deshpande S, Sok D, Ndung'u T, **Moore PL**, Murugavel KG, Patel V, Bhattacharya J. Distinct region-specific neutralization profiles of contemporary HIV-1 clade C against best-in-class broadly neutralizing antibodies. J Virol. 2025 Jun 17;99(6):e0000825. doi: 10.1128/jvi.00008-25

103 Chiaborelli M, Kopeka M, Sekhesa P, Sehrt M, Mohloanyane T, Ballouz T, Menges D, **Brown JA**, Belus JM, Gerber F, Raeber F, Williams A, Jackson-Perry D, Hyöky M, Conserve DF, Hampanda K, Amstutz A; and the Hair SALON Citizen Scientist Working Group. Hair salons as a promising space to provide HIV and sexual and reproductive health services for young women in Lesotho: a citizen scientist mixed-methods study. BMC Public Health. 2025 Jul 2;25(1):2202. doi: 10.1186/s12889-025-23435-3

104 Keller S, **Naidoo K**, Zekarias M, Israel-Isah S, Shaka M, **Gule G**, **Naidoo A**, Bathnna M, Dlamini-Miti JN, Yae K, Okpokoro E, Abimiku A, Bedru A, Tiemersma EW; TRiAD Study Consortium. Feasibility and acceptability of GeneXpert MTB/XDR implementation among healthcare workers in three low-middle income African countries. PLoS One. 2025 Jun 24;20(6):e0326342. doi: 10.1371/journal.pone.0326342

**Continued from previous newsletter*

For the complete list of publications see here: https://www.caprisa.org/Publication/1/1