

NEWSLETTER

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The 9th Edition of the EHVA NEWSLETTER

Welcome to the ninth edition of the **European HIV Vaccine Alliance (EHVA)** newsletter. EHVA is an alliance of 39 partners in Europe, Sub-Saharan Africa, and North America. We work collaboratively to contribute to the development of safe and effective vaccines aimed at stopping HIV infections and AIDS. Through a multidisciplinary platform, EHVA facilitates the development and evaluation of novel prophylactic and therapeutic HIV vaccines, with the aim to select at least two of the most promising vaccine candidates for clinical development.

We work closely with research partners across several Sub-Saharan African countries and with the European and Developing Countries Clinical Trials Partnership (EDCTP) to ensure that the vaccine candidates are relevant for and can be evaluated in countries where vaccines are most needed. The work of EHVA is funded through a 5-year grant from the European Union's Horizon 2020 program and the Swiss Government. To learn more about EHVA visit our website <http://www.ehva-a.eu>.

[EHVA Website](#)

EHVA NEWS & UPDATES

COVID-19 Update

As we approach the end of the year, the EHVA team offers its immense gratitude to consortium partners and the extended community of researchers and healthcare workers who continue to work tirelessly to care for patients impacted by COVID-19, gain new insights to guide medical practices, and develop new tools to overcome this pandemic. EHVA remains committed to patient care, with hospital centres associated with EHVA prioritizing the management of patients suffering from COVID-19.

We remain in regular contact with our collaborators and funders to assess the impact of COVID-19 on EHVA's work as the pandemic evolves. Our community partner European AIDS Treatment Group (EATG) is monitoring access to care and treatment for people living with HIV, supporting their needs to stay healthy, and providing up to date evidence related to COVID and HIV. You can find these updates in their quarterly [newsletter](#) or visit [this list](#) for additional resources, information, and support.

EHVA-T02 Therapeutic Trial Update

The initiation of the EHVA-T02 therapeutic HIV vaccine trial has been delayed as a result of the COVID-19 pandemic. The trial, which will evaluate a novel therapeutic regimen combining a vaccine candidate with an immunomodulatory therapy, is now set to enter clinical evaluation within the next few months. In consultation with EHVA's partners including the European AIDS Treatment Group, there is a recognition in the community that it is important that HIV research can continue during the COVID-19 pandemic, providing appropriate measures are in place to ensure the safety of trial participants.

In discussions within and outside EHVA, with researchers and communities representing people living with HIV, updated trial participant safeguarding measures have been developed in recent months. This includes the need to avoid exposing participants to unnecessary risks associated with regular hospital visits, as well as how to safely conduct and mitigate any potential risks due to COVID-19 in a trial with an analytic treatment interruption. Of note, on 6 November 2020, partners of the EHVA consortium and the International AIDS Society (IAS) took part in a consultation with the EATG and local HIV community representatives from Switzerland and the United Kingdom.

Attendees expressed consensus that appropriate safeguarding measures were in place for the conduct of EHVA-T02. Community support is now needed to disseminate information and monitor and support trial participants.

Inter-Laboratory Reproducibility of Inducible HIV-1 Reservoir Quantification by TILDA – Lungu, C. et al. (2020)

Substantial efforts to eliminate or reduce latent HIV-1 reservoirs are underway in clinical trials and have created a critical demand for sensitive, accurate, and reproducible tools to evaluate the efficacy of these strategies. A group led by Cynthia Lungu at Erasmus University Medical Center have developed one such assay, tat^{rev} induced limiting dilution assay (TILDA). TILDA measures the frequency of CD4+ T cells harbouring inducible latent HIV-1 provirus while circumventing limitations of existing quantitative assays. Cross-validation of the assay in two separate laboratories showed strong correlation, further supporting use of TILDA for reservoir quantification in multi-center interventional HIV-1 Cure trials.

Read the full article [here](#).



Brief Report

Inter-Laboratory Reproducibility of Inducible HIV-1 Reservoir Quantification by TILDA

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Prospective EHVA Prophylactic Clinical Trials

EHVA is currently completing its fifth year of research, during which the consortium has developed several novel vaccine concepts, including vector-based vaccine candidates, new delivery modality, and HIV envelope trimer-based vaccine candidates. The consortium hopes to complete three clinical trials by the end of the extended project period.

The two lead vector-based vaccine candidates are a DNA-launched RNA Replicon Vaccine (DREP) and a novel VSV-GP vaccine. The DREP vaccine is anticipated to be tested in a first-in-human clinical trial in early 2021. While the VSV-GP based vaccine will not be brought to clinical development within the lifespan of EHVA, it has shown promising results in non-human primate studies.

The new delivery modality is a vaccine based on dendritic cell-targeting developed by [VRI \(Vaccine Research Institute\)-Inserm](#). Phase I testing in healthy volunteers is due to begin in 2021.

Finally, the trimer vaccines include two Clade C trimers antigens (known as ConCv5-KIKO and a complementary germline-targeting trimer ConCv5_GTv1). The plan is to combine them to stimulate the generation of broadly neutralizing antibody responses targeting anti-CD4-BS, but also to enable the maturation of B-cells through sequential immunization with different HIV envelope proteins. GMP manufacturing of these two trimers is well underway, with the phase I trial anticipated to start in 2022.

HIV VACCINE & PREVENTION NEWS



Results from the [HIV Prevention Trials Network \(HPTN\) 084 study](#) in November demonstrated that a pre-exposure prophylaxis (PrEP) regimen of long-acting cabotegravir (CAB LA) injections once every eight weeks was safe and superior to daily oral tenofovir/emtricitabine (FTC/TDF) at preventing HIV acquisition in cisgender women in sub-Saharan Africa. Earlier this year, the [HPTN 083 clinical trial](#) likewise showed that a regimen of CAB LA PrEP injections once every eight weeks was superior to daily oral FTC/TDF for HIV prevention among transgender men and transgender women who have sex with men.

The [Dapivirine ring](#), a long-acting, woman-controlled method, received World Health Organization (WHO) prequalification on 30 November. [Recent evidence](#) demonstrates that greater dapivirine release from the long-acting vaginal ring is correlated with lower risk of HIV acquisition. This monthly, replaceable product could fill an important HIV Prevention gap, allowing discreet use to reduce HIV risk during vaginal sex.

PREVAILING AGAINST PANDEMICS

BY PUTTING PEOPLE AT THE CENTRE



World AIDS Day 2020 on 1 December was a historic one as we confront the ongoing COVID-19 pandemic and its profound impact on existing efforts to control and eradicate HIV/AIDS. The UNAIDS AIDS Day report, [Prevailing against pandemics by putting people at the centre](#), released at the end of November, calls on countries to make far greater investments in global pandemic responses and adopt a new set of bold, ambitious but achievable HIV targets for 2025. The people-centred targets focus on high coverage of HIV and reproductive and sexual health services and significant anti-discrimination and anti-stigma targets, particularly for those most at risk and marginalized. If those targets are met, the world will be back on track to ending AIDS as a public health threat by 2030. With nearly 700,000 deaths from AIDS-related causes and 1.7 million new HIV infections in 2019, the report also highlights the importance of investing in affordable and accessible HIV prevention interventions to address major gaps in achieving the 2020 HIV prevention coverage targets. Winnie Byanyima, Executive Director of UNAIDS, further assured the global HIV community at the ministerial meeting of the Global HIV Prevention Coalition earlier in November that HIV prevention will be prominent in [the next Global AIDS Strategy](#), slated for release in March 2021. However, any HIV prevention toolkit is incomplete without HIV vaccine research and development (R&D) at the forefront – the only way to end the HIV epidemic is with a vaccine.

UPCOMING EVENTS

Three major conferences are scheduled in 2021. Each conference will take place virtually, with IAS Science anticipating hosting in-person sessions in Berlin.



The [4th HIVR4P](#) will take place virtually on 27-28 January and 3-4 February 2021. HIVR4P // Virtual will bring together the world's leading prevention researchers, advocates, implementers, funders, and policy makers to explore the many aspects of the biomedical research paradigm. Owing to the multiple overlaps between HIV prevention and COVID-19 research, HIVR4P will add a new abstract category, "COVID research: Applying lessons from HIV prevention to SARS CoV-2". Standard registration continues to 11 January 2021, followed by late registration from 12 January.



CROI
Conference on Retroviruses
and Opportunistic Infections

[CROI 2021](#) is slated to take place in March 2021 and has already been confirmed to include a virtual option to allow participation and networking for those who attend remotely. Confirmation on the final format is expected in the coming months. In response to the COVID-

19 pandemic, COVID abstracts may also be submitted in the areas of basic science, clinical research, and epidemiology and prevention, among others. General abstract submission is open until 15 January 2021 with early registration available until 27 January.

11TH IAS CONFERENCE ON HIV SCIENCE (IAS 2021)

BERLIN, GERMANY / 18 - 21 JULY

Berlin is set to host the [11th IAS Conference on HIV Science](#) on 18-21 July 2021, pioneering a hybrid format with an online component. It is expected to convene 6,000 scientists, clinicians, public health experts, and community leaders from over 140 countries. This will be the first time that Berlin has hosted the IAS Conference on HIV Science, having previously hosted the 9th International AIDS Conference in 1993.

If you have any feedback, questions or suggestions, please contact us! We look forward to hearing from you!

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