



HIV VACCINE TRIALS NETWORK

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c/o Dr Michael Makanga Executive Director Global Health EDCTP3 Joint Undertaking Executive Director
Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d’Or
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Belgium

28 August 2025

Letter of endorsement

Dear Sir/Madam,

On behalf of HIV Vaccine Trials Network (HVTN), we are pleased to endorse the SPOTLIGHT proposal under the EDCTP3 call for proposal - [HORIZON-JU-GH-EDCTP3-2025-01-two-stage](#) - *Global collaboration action for the development of vaccines for reducing the disease burden of Tuberculosis in sub-Saharan Africa*.

The HVTN is a global clinical trial network focused on the development of preventive HIV and TB vaccines. A significant part of our research strategy is to ensure the inclusion of people living with HIV (PLWH) in the clinical development of vaccines intended to prevent tuberculosis, as this is critical to maximize the timely public health impact of such vaccines. As a long-standing cooperative initiative, the HVTN works across continents to accelerate vaccine development in collaboration with government agencies, academic institutions, civil society, and the pharmaceutical sector. Therefore, our overarching mission closely aligns with the GH EDCTP3 JU goals of reducing the individual, social, and economic burdens of infectious diseases in sub-Saharan Africa and enhancing global health security.

In this context, HVTN is leading a Phase IIa trial of H107e/CAF®10b in people living with HIV (PLWH), which is a critically important risk group for TB. The trial protocol is currently under active development, with financial support from the Division of AIDS at the National Institute of Allergy and Infectious Diseases, and national regulatory submissions are planned for Q1 2026 with first participant, first dose targeted for Q2 2026. This trial will run in parallel with the EDCTP-funded



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SPOTLIGHT trial in HIV-negative adolescents and older adults. Together, these studies will deliver critical safety, immunogenicity, and dose-selection data across two priority target populations.

We affirm our strong support for the SPOTLIGHT project and recognize this as a unique opportunity to maximize knowledge gains, inform licensure planning, and advance equitable access to next-generation TB vaccines in LMICs as is the core goal of the SPOTLIGHT proposal. We are therefore happy to support this project with leadership and financing of the Phase IIa study in PLWH and provide the data for a combined meta-analysis. Together, these datasets will provide a strong evidence base for dose selection and advancement to late-stage efficacy testing in a broad target population.

The proposed trial is funded through our current NIH Cooperative Agreement, with a projected value of at a minimum \$5,925,233. We confirm our logistical and operational readiness to conduct the study and reiterate our intent to ensure data-sharing and alignment with SPOTLIGHT's timelines and objectives. The role of HVTN in the SPOTLIGHT proposal is limited solely to financing and conducting the phase IIa trial in PLWH, as previously outlined. Besides involving key members of the SPOTLIGHT team in the study from now and until its completion and providing safety and immunogenicity data for integrated analysis (incl. CTR and exploratory data package), HVTN has no assigned tasks, deliverables, or milestones as detailed in Part B. Consequently, should the SPOTLIGHT proposal be successful in securing funding from EDCTP3, the HVTN will not participate in any subsequent grant agreement, which would go through the coordinator and/or SSI as beneficiary

We confirm to the best of our ability the following:

1. We will comply with the Horizon Europe Regulation (EU) No 2021/695; Council Regulation (EU) No 2085/2021 establishing the joint undertakings under Horizon Europe; the Model Grant Agreement for Horizon Europe and applicable Global Health EDCTP3 JU rules, including the relevant work programmes and in particular the call conditions therein.
2. We will keep all information received in the context of our involvement as contributing partner to the Global Health EDCTP3 JU confidential. This confidentiality obligation applies in particular but is not limited to the areas of Global Health EDCTP3 JU call topic preparation and publication, proposal submission and evaluation, and consortium formation. We further understand that this obligation strictly prohibits the release of



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confidential information to any legal entities save where specifically authorised by Global Health EDCTP3 JU. Internal dissemination of information within our organisation will be done on the basis of the “need-to-know” principle.

3. We are confident of our ability to fulfil the above commitments and further confirm our understanding that the Global Health EDCTP3 JU will allocate resources to the above topic based on these commitments.
4. The value of our contribution will be based on costs calculated in accordance with Article 6 of the Horizon Europe Model Grant Agreement.
5. We accept that additional modalities regarding the provision of our contribution may be defined in subsequent agreements or documents, such as a funding agreement and topic text.

Yours faithfully,



James G. Kublin, MD, MPH

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