

Dr. Henning Gädeke, Chair of the Global Health EDCTP3 Joint Undertaking Governing Board

c/o Michael Makanga

Global Health EDCTP3 Joint Undertaking

56 – 60 Avenue de la Toison d'Or

1060 Brussels

Belgium

29 September 2025

## Letter of endorsement (Proposal: SPOTLIGHT, # 101248866-2)

Dear Dr. Gädeke,

On behalf of the Gates Foundation and in accordance with Council Regulation (EU) No 2085/2021 of 19<sup>th</sup> November 2021 establishing the joint undertakings under Horizon Europe and specifically Article 9 therein, I hereby submit this letter of endorsement of the SPOTLIGHT applicants proposal to the Global Health EDCTP3 Joint Undertaking ("Global Health EDCTP3 JU").

Since its inception, the Gates Foundation has been steadfastly committed to accelerating the global decline in tuberculosis (TB). This resonates well with the Global Health EDCTP3's strategy over the last 20 years and its significant investment made in all types of medical interventions to end TB.

The Gates Foundation is significantly investing in clinical trials for TB vaccines throughout sub-Saharan Africa and are providing financial support for a Phase Ia/Ib clinical trial of the H107e/CAF®10b vaccine candidate, being conducted by the SPOTLIGHT applicants, Statens Serum Institut (SSI), Aurum and SATVI through a grant to SSI. H107e/CAF®10b is an adjuvanted protein subunit composed of eight TB antigens, none of which overlap with those in BCG) administered with CAF®10b, an innovative adjuvant. As such, this novel TB vaccine candidate has the potential to diversify the pipeline of TB vaccine candidates and the completed phase Ia showed encouraging safety and immunogenicity data supporting advancement of the vaccine candidate.

Specifically, the Gates Foundation is supporting the phase Ib trial conducted by SSI, which will assess the safety, reactogenicity and immunogenicity of H107e/CAF®10b. Data from this trial will support the advancement to the phase IIa trial outlined in the SPOTLIGHT proposal. This subsequent trial is planned to be implemented with support from Global Health EDCTP3, contingent upon a positive funding evaluation. The co-funding of the Gates Foundation is expected to be instrumental in facilitating the proposed activities within the SPOTLIGHT proposal as the safety and immunogenicity data from this trial will directly inform the SPOTLIGHT project's clinical and regulatory strategy, including regulatory submissions for the proposed Phase IIa trial. We recognize this as a critical foundation for continued vaccine development and success of the project.

The Gates Foundation's role in the SPOTLIGHT proposal is limited solely to providing funding to the beneficiary, SSI and through subawards, Aurum and SATVI, as previously outlined. The Foundation has no assigned tasks, deliverables, or milestones as detailed in Annex 1 Part A. Consequently, should the SPOTLIGHT proposal be successful in securing funding from EDCTP3, the Gates Foundation will not participate in any subsequent grant agreement which would go through the coordinator and/or SSI as beneficiary.

**We confirm the following:**

1. The Gates Foundation's overall financial contribution to SSI is EUR4,519,152 [USD \$X4.8]. This investment spans a period of 26 months from 11 February 2025 to April 2027. The contribution from the Gates Foundation is specified in the different cost categories in the SPOTLIGHT proposal (# 101248866-2) in Proposal Part B: Technical Description. Eligible costs incurred by Gates Foundation grantee SSI, their subcontractors or sub-awardees will be paid to SSI by the Gates Foundation (through the existing grant) and SSI will in turn pay its sub-contracts or sub-awards under this grant. SSI will therefore not require reimbursement by the GH EDCTP 3 JU for these activities. As such, these will be considered Financial Contributions as defined in the "Guide for Contributing Partners" in Q7 1c. Eligible costs are defined in the model grant agreement: [https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga\\_horizon-euratom\\_en.pdf](https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/agr-contr/general-mga_horizon-euratom_en.pdf).
2. We will keep information, reasonably considered confidential in nature, received in the context of our involvement with the Global Health EDCTP3 JU confidential. This confidentiality obligation applies in particular but is not limited to the areas of non-public 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 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 financial contribution will be considered by Global Health EDCTP3 JU 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 documents, such as references to an existing funding agreement with SSI.

Yours faithfully,



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Nina D. Russell, Director, TB/HIV Research & Development