



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

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

1060 Brussels

Belgium

September 29, 2025

Letter of endorsement

Dear Dr Gädeke and Dr Makanga,

On behalf of Statens Serum Institut, Artillerivej 5, 2300 Copenhagen S, Denmark [DK46837428] and in accordance with Council Regulation (EU) No 2085/2021 of 19th November 2021 establishing the joint undertakings under Horizon Europe and specifically Article 9 therein, we hereby apply to become a contributing partner to the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU). Our contribution relates to the SPOTLIGHT proposal under the call for proposals by EDCTP3 - [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.

Statens Serum Institut (SSI) has a more than century-long mission to prevent and control infectious diseases through research, surveillance, and the development of vaccines and diagnostics. In recent years, SSI has significantly expanded its global health focus, contributing to the advancement of equitable access to new health technologies in low- and middle-income countries (LMICs), with a strategic emphasis on tuberculosis (TB). These priorities align closely with the Global Health EDCTP3 Joint Undertaking (GH EDCTP3 JU) objectives, particularly i) reducing the individual, social, and economic burden of infectious diseases such as TB in sub-Saharan Africa through development and uptake of effective vaccines; and ii) Increasing global health security by supporting vaccine research that enhances preparedness and response capacity in LMIC settings.

Within this context, SSI’s participation in the SPOTLIGHT project includes a set of co-funded activities, categorized as In-Kind and Financial Cash Contributions related to development of the novel TB vaccine candidate H107e/CAF10b. These activities are supported by leading global health funders and are integrated with the EDCTP3-funded SPOTLIGHT activities, offering significant added value by reducing duplication, accelerating timelines, and increasing the robustness of vaccine development. More specifically,

- Open Philanthropy are co-financing manufacturing and scale-up enabling activities related to the H107 vaccine antigen, which are integrated with the proposed EDCTP-supported manufacturing activities of the CAF®10b vaccine adjuvant. Together, these efforts will advance manufacturing capacity of both core components towards readiness for a Phase IIb/III licensure trial.



- The Gates Foundation is co-financing a Phase Ib trial of H107e/CAF[®]10b, which provides essential early clinical data (safety and immunogenicity) to inform regulatory submission and assay development for the SPOTLIGHT trial and broader development planning.
- SSI intends to contribute with in-kind drug product H107e and buffer for the trial to reduce cost and de-risk product readiness for the SPOTLIGHT trial as well.
- SSI Vaccine Development Department and Quality Assurance plans to contribute by having a Quality Management System (QMS), equipment and facilities for the GxP activities for producing H107e, buffer and for this trial to be able to technology transfer and produce the CAF10b adjuvant. This includes support and maintenance of the systems and procedures for labeling and shipping of IMP H107e and buffer to clinical sites in the Spotlight trial.
- The HIV Vaccine Trials Network (HVTN) will co-finance a phase IIa study in people living with HIV (PLWH). This will run in parallel to the SPOTLIGHT trial and provide essential safety and immunogenicity data in a key target population to be included in a meta-analysis for dose selection as well as regulatory submission for the planned licensure Phase IIb/III trial.

Together, the co-funded contributions strengthen the feasibility, scalability, and regulatory readiness of the vaccine candidate, ensuring that the SPOTLIGHT project is embedded in a broader, well-capitalized development ecosystem that will ultimately increase the public health impact in line with the ambitions of the Global Health EDCTP3 JU.

We estimate the total value of this contribution to be 8.931.296 euro.

* Please note that the discrepancies between the above-mentioned number and the application budget is due to the EDCTP template automatic calculation of OH. The funding declared as the Financial Contribution is granted by funders that do not share EDCTPs OH policy.

The contributions are as follows:

- **Financial contributions from funders: 8.627.487 euro**
 - **BMGF** funded contribution total: 4.519.152 (SSI: 2.110.178 euro and AURUM: 2.408.974 euro)
 - **Open Philanthropy** funded contribution: 847.779,9 USD (786.330,08 euro)
 - **HVTN** funded contribution: 5.925.233 USD (5.495.753 euro)
 - **SSI** contribution: 235.225,92 euro
- **In-kind contribution (own resources): 303.809 euro**



Contributing partner name: Statens Serum Institut Consortium member receiving the vials: Arum, SATVI, NIMR (Clinical trial sites WP 3)		
Budget Category	Cost (€)	Description
UNIT cost	Total cost: 303.809 euro Price per vial for H107: 379 euro resulting in 284.004 euro. Price per vial for buffer: 99 euro resulting in 19.805 euro.	The H107 and buffer vial will be sent to the projects clinical trial sites. The consortium member receiving the vials are: Aurum, SATVI, NIMR.

SSI confirms the following:

1. SSI 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 to the extent reasonably compatible with SSI's existing legal obligations in connection with the co-funding, in-kind and financial contributions.
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 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. SSI intends and expects to be able 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 calculated with reference to the cost principles set out in Article 6 of the Horizon Europe Model Grant Agreement, to the extent reasonably compatible with obligations connected to the co-funding, in-kind and financial contributions.
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,

Henrik Ullum
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