

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: ADVANCE-TB, # 101248871-2)

Dear Dr. Gädeke,

On behalf of the Gates Foundation 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, I hereby submit this letter of endorsement of the ADVANCE-TB 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, including the co-funding of trials involving adolescents and adults to advance BioNTech's BNT-164 vaccine candidate. Utilizing advanced messenger RNA (mRNA) therapeutics technology, BNT-164 offers an innovative strategy aimed at preventing active TB disease in both adults and adolescents and may serve as a critical component in achieving global TB control goals.

In particular, the Gates Foundation is supporting the Phase IIa clinical trial initiated in March 2025, the BNT164-02 Part B expansion trial conducted by BioNTech, which will enable the selection of the vaccine candidate for the Phase 2a trial outlined in the ADVANCE-TB 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 mRNA platform and dose selection as a prerequisite for the proposed project.

The Gates Foundation's role in the ADVANCE-TB proposal is limited solely to providing funding to the beneficiary, BioNTech, as previously outlined. The Foundation has no assigned tasks, deliverables, or milestones as detailed in "Proposal Part B: Technical Description". Consequently, should the ADVANCE-TB proposal be successful in securing funding from EDCTP3, the Gates Foundation will not participate in any subsequent grant agreement.

We confirm the following:

1. The Gates Foundation's overall financial contribution to BioNTech is EUR € 2,770,966.87 [~USD \$3.2M]. This investment spans a period of 24 months from 01 January 2026 to 31 December 2027. (See the detailed table attached to this letter for the breakdown).
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 existing funding agreement(s) with BioNTech.

Yours faithfully,



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

Gates Foundation Contribution to BioNTech SE as the Beneficiary		
Budget Category	Cost (€)	Description
Purchase costs (Travel, Equipment, Other goods, works & services)	€ 92,348.52	Travel and subsistence for annual collaboration meeting, face-to-face meeting for joined clinical data review and BNT team/program strategy meeting, on-site consultation service for co-monitoring and trial oversight, consultation for IP maintenance & strategy .
Subcontracting costs	€ 2,655,531.22	Service fees for Clinical Research Organization (<i>ICON</i> (Republic of Ireland)); supporting execution and oversight of the BNT164-02 PhIIa trial), Central Laboratory (<i>Cerba/BARC</i> (South Africa)); clinical sample analysis, processing, transport and storage), Clinical Manufacturing Organization (<i>Almac</i> (UK); clinical trial supply labelling, handling & shipment), IRT Vendor (<i>4G Clinical</i> (The Netherlands); IRT system maintenance to manage subjects and supply logistics) and Vendors for immunogenicity analysis (<i>Synexa</i> (South Africa) and <i>South African Tuberculosis Initiative</i> (SATVI; South Africa)).
Indirect costs (25% applied on Purchase costs)	€ 23,087.13	The Gates Foundation applies a lower IDC rate on its grants, which includes all cost categories. Therefore, there will be a discrepancy between the EDCTP IDC rates and the Gates grant total.
Total (€)	€ 2,770,966.87	

This in-kind contribution is critical to generate the data required to make the platform and dose selection for the proposed ADVANCE-TB trial.

Total contributions from the Gates Foundation to the Beneficiary (BioNTech) during 36 months from March 2025 (The proposal submission deadline) until December 2027 (the end date of the Gates Foundation grant) is EUR 10,836,533 [USD \$11.7M], however to address our understanding of EDCTP3's request to only consider contributions that fall in the anticipated timeframe of the proposed project, we have only included costs from early 2026 (anticipated start of ADVANCE-TB project) through to the end of 2027.