

BioNTech SE · An der Goldgrube 12 · 55131 Mainz Germany

Reference number: GH0 2025 001

Henning Gädeke, Chair of the GH EDCTP3 JU Governing Board

Contact: Erin Shutes
Department: Global Health Office

Through Michael Makanga, GH EDCTP3 JU Executive Director

Phone: +49 (0) 6131 9084-0
Fax: +49 (0) 6131 9084-390
Email: erin.shutes@biontech.de
Website: www.biontech.de

Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d'Or
Brussels – 1060

Date: September 29, 2025

Subject: Letter of Endorsement for HORIZON-JU-GH-EDCTP3-2025-01-TB-01-two-stage: Global Health EDCTP3 for “Global collaboration action for the development of vaccines for reducing the disease burden of Tuberculosis in sub-Saharan Africa”

Dear Dr. Gädeke,

On behalf of BioNTech of
An der Goldgrube 12
D-55131 Mainz
Germany

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 an application to become a contributing partner to the Global Health EDCTP3 Joint Undertaking (Global Health EDCTP3 JU).

BioNTech SE (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discoveries and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, several protein-based therapeutics, including bispecific immune checkpoint modulators, targeted cancer antibodies and antibody-drug conjugate (“ADC”) therapeutics, as well as small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases, including vaccine candidates against malaria, tuberculosis, HIV, and mpox, alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Duality Biologics, Fosun Pharma, Genentech, a member of the Roche Group, Genivant, Genmab, OncoC4, Regeneron and Pfizer. BioNTech entered into a collaboration with the Gates Foundation for the development of a mRNA-based tuberculosis vaccine in 2019, that resulted in the development of two clinical candidates BNT164a1 and BNT164b1, currently being evaluated in two Phase I trials and a Phase IIa trial.

The potential added value towards the contribution of achieving GH EDCTP3 JU by BioNTech is:

- Progressing clinical development of a potentially promising mRNA vaccine candidate against

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tuberculosis towards an efficacy/licensure trial supporting an “all comers” label.

- Deepening the knowledge of site level TB epidemiology to inform the design of the licensure trial. The data generated can be leveraged by other TB vaccine developers.
- Generation of data on chest X-ray findings and their association with *Mtb* sputum positivity to support regulatory acceptance of a novel TB endpoint for future TB efficacy trials. This will additionally support policy decisions by providing critical data on asymptomatic TB.
- Site level capacity strengthening to support performance of safety labs locally and evaluate less complex methodologies for cellular mediated immune (CMI) response assessment in clinical samples. This will potentially support the reduction of clinical trial costs not only for the proposed project but also for future trials (and for other vaccine developers).
- Establish sustainable and mutually beneficial collaboration between clinical research centers, academia and industry partners across sub-Saharan Africa and Europe.

With the submitted proposal BioNTech is applying for a **total grant amount of € 22,268,986** over a project period of **5 years**. Outlined in Table 1 are project work packages that are led by BioNTech, detailing items/topics and entities to be funded with this project.

Table 1: Specifics of proposed involvement (work packages and topics/entities) to be funded under the project proposal.

Work package	Topics/Entities to be funded
Safety & reactogenicity (WP 1) and immunogenicity (WP 2) of a mRNA TB vaccine (BNT164a1 or BNT164b1) in IGRA-negative, HIV-negative adults and PLWH	Clinical Research Organization (CRO): The CRO will be tasked with supporting execution and oversight of the proposed trial, including: perform on-site monitoring, data management, biostatistics, regulatory support, safety reporting support, and other functions related to operationalization of the clinical trial. Central Laboratory: TBD. Central lab will be located in South Africa. Activities will include biological sample collection kits, supply of reagents to all PBMC labs, courier services from sites to central lab and from central lab to specialty lab for immunogenicity endpoints. Furthermore, cost will be incurred for clinical sample biobanking for potential future analyses (e.g. transcriptome analysis). Key cost drivers will be shipping and testing services. CMO: Will perform packaging, labeling, storage and distribution of the investigational medicinal product (IMP). Costs also cover clinical pharmacists, demo kits, placebo and ancillaries. IRT Vendor: Will provide RTSM solutions, building and maintaining the IRT system for the clinical study. The IRT system helps to manage subjects and supply logistics, e.g. randomize subjects to treatment arm and triggers drug shipments automatically to sites per user configuration. Vendor for secondary immunogenicity endpoint analyses of clinical samples (cell-mediated immunity and humoral responses): Analysis will be performed by a vendor that is ideally located in Africa and has developed and validated the immunological assays currently in use in the BNT164 ongoing trials (e.g. Synexa Life Sciences). Contract costs are estimations based on a quote provided by Synexa Life Sciences. Costs include T cell responses measured by intracellular cytokine staining assay (ICS) as well as antibody responses measured by multiplex electrochemiluminescence (ECL) assay for samples from 500 participants and five time points. Purchase cost items: including ESAT-6 free tubes, customized peptide synthesis for ICS and MSD plates for ECL assays, reagents & materials to perform ICS/ECL, travel to investigator meetings (total of 2) and one

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	site initiation meeting.
(WP 3) Site level TB epidemiology; <i>Mtb</i> infection prevalence and incidence (exploratory)	JPT: Will manufacture and aliquot the peptides included in the ESAT6-free IGRA test for measuring sensitization to <i>Mtb</i> antigens after vaccination with the IMP.
(WP 5) Local research capacity strengthening. (b2) PBMC processing training (c1) PBMC-ICS	Includes training materials, consumables, equipment for PBMC isolation and qualification of operators for trial endpoints. Additionally, sites will be trained on the ICS assay. The costs include reagents, materials and equipment for cell culture and flow cytometry.
(WP 7) Consortium coordination and scientific project leadership	Includes personnel costs for Consortium Management (0.7 FTE; Program Management) and a Financial Grant Manager (0.5 FTE) to ensure successful execution of project, provision of financial controlling and reporting to funder. Also travel, subsistence and service costs for annual consortium meeting (total of 4).

BioNTech will incur in-kind costs associated with activities outlined in the ADVANCE-TB proposal. BioNTech estimates the value of this contribution to be ~€ 18.4m over the 5 years of this project. BioNTech shall ensure that our cash and in-kind contribution are eligible in accordance with Article 6.1 of the Horizon Europe Model Grant Agreement.

In addition to the in-kind costs to be incurred as part of specific activities outlined in the proposal (as above), BioNTech will also contribute in-kind costs associated with generating data critical to the proposal. BioNTech, together with the Gates Foundation, has invested in the development of the two mRNA-vaccine candidates BNT164a1 and BNT164b1 that are currently being evaluated in Phase Ia/b (BNT164-01, NCT05537038; and BNT164-02 Part A, [NCT05547464](#)) and Phase IIa clinical trials (BNT164-02 Part B, [NCT05547464](#)). The Ph IIa clinical trial initiated in March 2025 (BNT164-02 Part B) directly supports the ADVANCE-TB proposal by contributing data critical to enable final selection of the mRNA platform (either BNT164a1 or BNT164b1), dose and regimen to be evaluated in WP1 and WP2 of this project. The mRNA platform and dose selection are a prerequisite for the proposed project and BioNTech's in-kind contributions associated with this critical data. Table 2 summarizes the total BioNTech in-kind contribution in a detailed cost breakdown.

Table 2: Overview of estimated in-kind contributions of BNT to the proposed project assuming 5-year project duration.

BioNTech SE		
Budget Category	Cost (€)	Description
Personnel costs	€ 19,043,150	BNT employees assigned to the ADVANCE-TB project and the BNT164-02 PhIIa study including indirect cost.
Purchase costs (Travel, Equipment, Other goods, works & services)	€ 1,553,819	Travel and subsistence for annual collaboration meeting with the Gates Foundation, face-to-face meeting for joint clinical data review and BioNTech team/program strategy meeting for BNT164-02 PhIIa study. ADVANCE-TB project travel costs for joint steering committee meeting, joint data review meeting, team/program strategy meetings and site initiation visits. on-site consultation service for co-monitoring & trial oversight costs, service fees for maintaining existing patents for BNT164 and

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		additional IP services BNT164-02 PhIIa and ADVANCE-TB project. Halal Certificate for IMP for ADVANCE-TB project.
Subcontracting costs	€ 4,505,531	IMP manufacturing for ADVANCE-TB project including plasmid, drug product (DP) formulation, DP stability study, and potency assay development. Service fees for Clinical Research Organization (ICON (Republic of Ireland); supporting execution and oversight of the BNT164-02 PhIIa trial), Central Laboratory (Cerbera/BARC ; clinical sample analysis, processing, transport and storage), Clinical Manufacturing Organization (Almac (UK); clinical trial labelling, handling & shipment), Vendor of interactive response technology (4G Clinical (The Netherlands); IRT system maintenance to manage subjects and supply logistics) and Vendors for immunogenicity analysis (Synexa, South African Tuberculosis Initiative (SATVI) , both South Africa).
Other cost categories (internally invoiced goods and services)	€ 320,000	Drug substance manufacturing, other operational expenses (analytical & process development).
Indirect costs (25% applied on costs)	€ 388,455	25% applied only on purchase cost
Total (€)	€ 25,810,955	

The in-kind contributions of BioNTech to the ADVANCE-TB proposal sum up to a total of ~€ 25.8m.

BioNTech's investment in this Phase IIa (BNT164-02 Part B) is supported by funds provided by the Gates Foundation (additional ~€ 2.8m) resulting in a total combined investment of ~€ 28.6m. The Gates Foundation letter of endorsement will be sent separately.

BioNTech confirms the following:

1. That BioNTech 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 the applicable Global Health EDCTP3 JU rules, including the relevant work programmes and in particular the call conditions therein.
2. That BioNTech will keep all information received in the context of our involvement as contributing partner to the GH EDCTP3 JU confidential. This confidentiality obligation applies in particular, but is not limited to, the areas of GH 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 GH EDCTP3 JU. Internal dissemination of information within our organisation will be done on the basis of the "need-to-know" principle.
3. BioNTech is confident of our ability to meet the above commitments and further confirm our understanding that the GH EDCTP3 JU will allocate resources to the above topic based on these commitments.
4. That the value of our contribution will be based on costs in accordance with Article 6 Horizon Europe Model Grant Agreement on eligibility of costs.
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.

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Kind regards,

Signed by Dr. Sierk Poetting

 I approve this document
30-Sep-2025 | 06:45 CEST

Dr. Sierk Poetting
Chief Operating Officer

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Signed by Dr. Oliver Hennig

 I approve this document
30-Sep-2025 | 07:05 CEST

Dr. Oliver Hennig,
Prokurist

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