



BioNTech SE · An der Goldgrube 12 · 55131 Mainz Germany

Chair of the GH EDCTP3 JU Governing Board
Through the GH EDCTP3 JU Executive Director
Global Health EDCTP3 Joint Undertaking
56 – 60 Avenue de la Toison d’Or
Brussels – 1060

Reference number:

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Date:

May 28, 2024

Re HORIZON-JU-GH-EDCTP3-2024-02-01-two-stage: Global Health EDCTP3 JU Training Fellowship with return phase

Dear sir/madam,

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

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

Biopharmaceutical New Technologies (BioNTech) is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. BioNTech exploits a wide array of computational discovery 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, innovative chimeric antigen receptor (“CAR”) T cells, several protein-based therapeutics, including bispecific immune checkpoint modulators,

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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, Genevant, Genmab, OncoC4, Regeneron and Pfizer.

The potential added value towards the contribution of achieving GH EDCTP3 JU by BioNTech is: BioNTech aims to contribute to the vision of the MAV+ of strengthening local pharmaceutical systems and manufacturing capacity revolving around the workstream focusing on R&D, higher education, and skills. BioNTech will directly participate in the project implementation, as will be mutually agreed with the other consortium members, by offering internships supported by mentorship programs, in mRNA vaccine development targeting multiple infectious diseases including HIV, Malaria and TB (see table 1). We aim to support the following objectives:

- Increase the number of skilled clinical researchers and innovators in sub-Saharan Africa.
- Promote the career development and retention of skilled personnel in sub-Saharan Africa; the plan for the return home phase should be flexible and developed together with other consortium members, BioNTech SE and the fellows.
- Strengthen sub-Saharan African countries clinical human capital base in Research and Innovation (R&I).
- Establish sustainable and mutually beneficial collaboration between clinical research centers, academia, and Industry Partners across sub-Saharan Africa and Europe.

To note, BioNTech has ongoing experience in running capacity building initiatives targeting Sub-Saharan Africa such as Afrika Kommt! and World Health Organization TDR Clinical Research and Development Fellowship programme. Another program BioNTech has been running for past years is BioNTech’s own ATLAS (Talent Academy for TransLational Science), which guides and supports PhD students to conduct research projects and offers comprehensive training in BioNTech technologies. BioNTech SE and TRON partnered to oversee this scientific training program with a strong focus on "the art of translation", i.e. turning basic scientific discoveries into applications. At BioNTech there are dedicated personnel who ensure that processes are established for the implementation of formal academic programs in the company. BioNTech is currently hosting master’s students, some as working interns and others to conduct projects as a mandatory component of the curriculum.

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If successfully placed in a consortium, together with collaborating partners BioNTech commits to:

- Contribute to a high-quality training programme related to R&D on diseases in the scope of the Global Health EDCTP3 JU at master level in global health/clinical research.
- Develop an open, fair, and transparent procedure for selecting the fellows coming from different geographical regions of SSA, based on quality, in line with the prospective fellow professional development plans and with appropriate gender balance.
- Communicate the number fellows, the cost of the training in the industry placement and the scope of support to be provided to fellows. for the return phase.
- Establish linkages with other Global Health EDCTP3 JU actions foreseen as relevant.

Please see Table 1 below are foreseen project areas / skill development that we plan to offer:

Table 1

Stage of Vaccine Development	We can offer internships for 6 to 12 months for the following skills	Where and when
Pre-Clinical	1. Bioinformatics and AI	Mainz, Germany
Clinical Trials	2. Project Management in Clinical Trials 3. Clinical Operations 4. Regulatory aspects in vaccine development 5. Clinical Development 6. Clinical Trial Supply Management	Mainz Germany OR suitable regional affiliate (with possibility of supporting CTs in Africa)
Manufacturing scale up	7. mRNA manufacturing 8. Manufacturing Quality Assurance & Quality Control	Manufacturing facilities in Germany OR suitable regional affiliate

BioNTech proposes not to transfer funds to others in the consortium, except directly to the prospective fellows who will be recruited later from entities i.e. that are not necessarily signatories to the grant agreement. BioNTech will also incur in-kind costs associated with project activities.

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BioNTech estimates the value of this contribution to be EUR **2,235,600** over the 3 years of this programme. 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. See table 2 for cost breakdown.

1. A contribution of EUR **891,000**.

- a) Money transfer to the fellow, in form of monthly stipends for sustenance.
- b) Relocation support for the prospective fellow

2. An contribution of EUR **1,344,600**.

a) Personnel costs attributed to

The time of supervisor, preceptors , mentorship with the expertise required to support skills training indicated in table 1.

b) Purchase costs attributed to

Lab based project space, equipment, consumables which are likely to be_QC or QA related projects.

Equipment i.e. IT devices and accessories

c) Management and administrative costs attributed to

The time of legal and IP employees who will be involved in the setting up of consortium, grant agreements and contracts with the fellows.

The time of IT; HR and payroll employees that will be involved in setting up the prospective fellow to access BNT resources and associated BioNTech onboarding trainings for new persons in the company.

Table 2

The table provides overview for potential maximum, financial contributions, and in-kind contributions, which will vary to the number of students and number of years of as mutually agreed by the consortium.

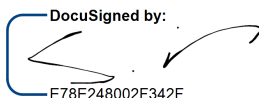
Costings are based on the estimated number of master's students - incremental per year - Refer to table 1 for breakdown of skills training offered.
Costings are based on max number of months a master's student is at BNT i.e. 12 months.
Costings for Lab projects estimated at one per year.
 Amount is in Eur

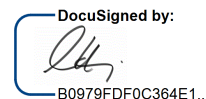
	1 st Year	2 nd Year	3 rd Year	Total
Number of Students	8	10	12	30 students
Cash contributions				
Personnel costs Monthly stipend	211,200	264,000	316,800	792,000
personnel costs Relocation support	26,400	33,000	39,600	99,000
Subtotal cash contribution				891000
In kind contributions				
Personnel costs Supervisor, Preceptor Mentorship	320,000	400,000	480,000	1,200,000
Purchase cost. Lab based project space, equipment, consumables.	35,000	35,000	35,000	105,000
Management and administrative costs legal, payroll, Onboarding process costs e.g. trainings, IT set up, equipment 5% of salary	10,560	13,200	15,840	39,600
Subtotal in kind contribution				1,344,600

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.

Yours faithfully,

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Dr. Sierk Poetting
Chief Operating Officer

Dr Oliver Henning
Senior Vice President Product Supply

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