BERLIN INSTITUTE OF HEALTH AT CHARITÉ

ANNOUNCEMENT

NATIONAL TRANSLATIONAL TANDEM PROGRAM FOR GENE AND CELL-BASED THERAPIES (nTTP-GCT)

– FUNDING GUIDELINE –

This is a translation of selected parts of the full German version of the funding program that was published October 1st, 2024. Please note that the German version of the "nTTP-GCT-Förderrichtlinie" is the legally binding one.

1. FUNDING OBJECTIVE, PURPOSE OF FUNDING, LEGAL BASIS

1.1 FUNDING OBJECTIVE AND PURPOSE OF FUNDING

In order to accelerate the translation of gene and cell-based therapies (GCT) into medical care, which is urgently needed in Germany, and to strengthen Germany's position in international competition as a location for research and innovation, the Berlin Institute of Health at Charité (BIH) has coordinated the development of a National Strategy for Gene and Cell-Based Therapies on behalf of the BMBF in a multi-stakeholder approach. This strategy pursues a holistic concept that integrates and connects all parts of the value chain, from basic research to patient care.

As part of the strategy's field of action II ("Ausbildung und Kompetenzstärkung"), measures have been developed to establish training and continuing education programs for junior and specialist staff in the field of GCT. The design and implementation of an innovative interaction program for Junior Clinician Scientists (JCS) and Translational Scientists (TS) is one of these measures and is being implemented by the BIH Biomedical Innovation Academy (BIA). The BIA acts as a think tank for strategic academic personnel development in biomedicine and has a broad funding portfolio and many years of experience in developing funding programs tailored to specific target groups and career phases (including the renowned BIH Charité Clinician Scientist Program with its various funding lines).

The aim of the funding measure is to provide young scientists with a high level of research interest in the GCT area with the necessary time to pursue their research and thus support them in their careers and professional networking.

In particular, this should expand specific expertise in the field of GCT and strengthen nationwide translational networking structures between basic research and clinical practice, as well as between academia and industry.

The success of the funding measure will be determined by the high rate of successful program graduates and by their number of publications, patents and conference contributions, the number and amount of third-party funding acquired and/or the type of subsequent professional positions.

1.2 LEGAL BASIS

NOT TRANSLATED

2. TYPE OF FUNDING

Within the framework of this national funding line, **tandems of junior clinician scientists (JCS) and translational scientists (TS)** with interest in research are supported in jointly working on a research project in Germany in the GCT thematic area with a strong translational character. The funding program includes an exemption from work ("protected time") agreed with the respective employers to work on this project, as well as further training and networking opportunities.

A **tandem consists of one JCS with a doctorate and one TS with a doctorate**, with the specific aim of working together on a translational project in the GCT area.

The **Junior Clinician Scientist** is a licensed physician in the first three years of specialist training.

The **Translational Scientist** (Medical Scientist) is a scientist in his/her postdoc phase and not involved in patient care. There are no restrictions regarding the TS's field of specialization.

Since the aim of this funding measure is to provide targeted support for the careers and networking of an excellent research tandem, the grants are personal. When submitting the application, the candidates of the applying institutions for the JCS and TS positions must be named. The tandem partners must work on a joint project and can come from the same institution or from two different organizations. In the latter case, it is important that the two institutions agree on their candidates in advance and submit the application together. Applications with tandems from different organizations (in particular from research institutes in different federal states or academia-industry collaborations) are particularly welcome.

Multiple applications from one institution are possible as long as each individual application is for the funding of a different tandem with its own project.

Research projects with a translational character are considered to be projects that have a relevant medical impact on patients or the general population. These may be subprojects of clinical studies or projects for the development, improvement and/or validation of therapies, therapeutics or diagnostics, for example. They may also include manufacturing and quality control processes that are necessary to bring the corresponding GCT products or procedures into medical care. The research project is not subject to any restrictions with regard to the medical specialty.

In principle, parallel funding of the research project under the "Nationalen Förderung von Translationsprojekten zur Therapie mit gen- und zellbasierten Produkten und assoziierter Diagnostik" is possible, provided that the requirement for ten percent co-financing is met for both programs (see Chapter 4.2) and double funding of persons is excluded.

Pure basic research and the founding of start-ups or spin-offs are not supported.

According to the National Strategy, GCT includes the following procedures:

- Therapy approaches with advanced therapy medicinal products (ATMPs):
  - Somatic cell therapeutics (e.g. in the form of stem cells, cells of the immune system or mesenchymal stromal cells)
  - Gene therapy medicinal products in the form of replacement, addition or suppression therapies using viral and non-viral vectors or genome editing
  - Tissue engineering products such as the production of tissues for surgical use, including the use of novel biomaterials
- Therapeutic approaches with novel biological products, such as mRNA and other nucleic acid-based methods, extracellular vesicles or exosomes, used in the context of a gene and cell-based therapeutic procedure
- Further approaches of this kind in the context of gene and cell-based therapies

The following procedures are excluded from funding:

- Approaches that are developed for other purposes than gene and cell-based therapies (e.g. mRNA vaccinations against infectious diseases)
- Approaches that are based **exclusively** on small molecules and/or recombinant proteins (including antibodies)

3. RECIPIENT OF FUNDING

NOT TRANSLATED

4. SPECIAL FUNDING REQUIREMENTS

4.1 RIGHTS OF EXPLOITATION

If jointly processed translational research projects are based on jointly held relevant patents (academia/private person/company), funding can only be provided for tandems in which academia holds the majority of the relevant patents and IP. In the event that patents and IP are generated during the funding period, there must be a contractual agreement under which the corresponding rights will lie with academia and thus a subsequent exploitation will also be carried out by the academic institution.

4.2 FINANCING

According to § 7 (3) of the "Verwaltungsvereinbarung über die Rahmenbedingungen für die Weiterentwicklung des Berliner Instituts für Gesundheitsforschung (BIG)" funding by the BIH for institutions based outside the state of Berlin requires that the institution to be funded or the respective federal state is willing to cover 10 percent of the funding. The assumption of the financing share is to be confirmed as part of the application process. For institutions based in the state of Berlin, the financing share is already deemed to have been provided through the funding of the BIH by the state of Berlin.

4.3 GUARANTEES FROM THE APPLICANT INSTITUTIONS

When submitting their application, the applicant institutions must provide written confirmation of the following:

- their candidates' employment for the entire funding period
- the financing of the research project (no infrastructure or material resources for the implementation of the research project will be provided as part of the funding)
- assure that in the event of funding, they will grant their candidates "protected time" of 20 percent for a JCS (release from clinical duties) or 50 percent for a TS (each based on a full-time position) and take this into account when planning the funded person's work schedule, and taking steps to document the protected time. The "protected time" financed by the program may explicitly not be used to carry out tasks financed by the federal state
- ensure that the conditions for the tandem partners from different organizations to work together (e.g. a cooperation agreement signed by both parties) are already in place or will be in place at the latest by the start of the funding
- confirm that all legal requirements for the implementation of the research project are met.
- confirm that their candidates are not receiving double funding for their position

4.4 PART-TIME EMPLOYMENT

In principle, it is possible to participate in the funding program while working part-time. However, for the JCS, part-time employment must be at least 40 percent of a full-time position, whereby only the clinical portion can be reduced. The "protected time" for research of 20 percent (based on a full-time position), which is covered by the program, cannot be reduced by working part-time. The program duration of two years is not extended by working part-time.

For the TS, part-time employment can be a maximum of 50 percent of a full-time position. It must be ensured that 50 percent of the working hours (based on a full-time position) are available exclusively for the joint research project.

4.5 ABSENCE OR DROP-OUT OF A FUNDED PERSON

Since the program duration, including job financing, applies equally to both tandem partners, the program cannot be interrupted unilaterally. A longer absence of a funded person, e.g. due to illness or parental leave, would put the success of the project and the financing of the second person into risk.

In the event of a long-term or permanent absence of a funded person (> 6 weeks), their employer must therefore propose an adequate replacement to the program management, who will join the program (temporarily or permanently) and ensure the ongoing implementation of the project.

If a funded person changes him or her employer, it is generally possible and desirable for the funded person to continue the program at the new place of work, provided that the conditions for carrying out the program and the research project exist at the new place of work and are formally confirmed by the new employer.

4.6 PARTICIPATION AND REPORTING OBLIGATIONS

Funded persons are expected to participate in the development and expansion of the national GCT network and expertise and to take part in the regular digital jour fixe events (see chapter 5c).

Each funded person shall regularly enter relevant information on his/her career progress (e.g. publications, grants, prizes and acquisition of additional skills in the field of GCT) in the BIH Application and Reporting Portal.

In addition, each tandem prepares a joint interim report on the current status of their research project and their networking activities once a year. At the end of the funding period, a jointly authored final report on the research project is submitted via the BIH Application and Reporting Portal.

4.7 OTHER REQUIREMENTS

For the clinical and/or scientific development of the fellows, their support by two mentors each is expected.

Details on the application and the requirements, e.g. for mentors, can be found in the “Application Guideline/Hinweise zur Antragstellung”.

5. TYPE AND SCOPE, AMOUNT OF FUNDING

Funded tandems receive support within the program with regard to a) their job funding with secured research time, b) funding for project-relevant travel, and c) training and networking activities.

a) Personnel Costs

JCS are funded at 20 percent[1] of a full-time position by the program and must continue to be funded by the clinic at 80 percent (for full-time employment). The clinic must ensure the employment contract and also a 20 percent release from clinical duties ("protected time") for the implementation of the planned research project. The mode of this release will be defined at the beginning of the funding in an individual target agreement (between the funded person, the associated institute directorate/disciplinary manager, the mentors and the BIA program directorate) and signed by all parties. Pro-rata funding is provided based on the personal prerequisites of the funded person and on the collective bargaining agreements applicable to university hospitals in the respective federal state. The funding relates to the pure gross salary without surcharges (Ä1 or equivalent). In cases where a different remuneration applies, the maximum personnel costs covered by the program are based on the above-mentioned regulation.

TS are financed by the program at 50 percent[1] of a full-time position and 50 percent (for full-time employment) must continue to be borne by the employer. The employer must ensure both the employment contract and a 50 percent release from work for research ("protected time") from the area of responsibility for the implementation of the planned research project. The mode of this release will be defined at the beginning of the funding in an individual target agreement (between the funded person, the associated disciplinary manager, the mentors and the BIA program management) and signed by all parties. Pro-rata funding is provided based on the personal prerequisites of the funded person and on the collective bargaining agreements applicable in the respective federal state (salary group E13-E14 TV-L or equivalent). The funding relates to the pure gross salary without surcharges. In cases where the remuneration of the funded person is not based on TV-L, the maximum personnel costs covered by the program correspond to the highest level of the E14 TV-L salary group).

b) Travel

To promote interdisciplinary and cross-location networking, project-related trips are financially supported. It is also possible to receive funding for a work visit for scientific exchange. A total of up to € 1,500 in travel funds can be applied for and used per tandem partner. The application and subsequent report are submitted via the BIH Application and Reporting Portal.

c) Training and Networking Activities

Funding recipients are supported in developing their expertise, particularly in the areas of translation and GCT. This includes the opportunity to participate in seminars, workshops and training courses in relevant GCT subject areas.

In addition, the funding recipients are expected to participate in a national network and competence building. Among other things, a digital jour fixe takes place regularly, during which the tandems present their research projects to the other program participants, the program management, experts and stakeholders.

[1] See the special conditions for recipients of funding outside Berlin in Chapter 4.2

The program duration is 2 years. The start of funding is planned for February 1, 2025, subject to local administrative conditions.

In exceptional cases, a delay of up to three months is possible.

Reconciling Family and Program Participation

In principle, the program can be completed part-time (see Chapter 4.4), provided that the respective "protected time" required and financed by the program for project work is ensured.

Where possible, childcare is provided for the participants' attendance at on-site events organized by the program.

[…]

6. OTHER FUNDING REGULATIONS

NOT TRANSLATED

7. PROCEDURE

The funding program is carried out by the Biomedical Innovation Academy of the Berlin Institute of Health (BIH) on behalf of the BMBF.

The contact person is the program coordinator

Gabriela Böhme (nttp-gct@bih-charite.de, phone: 030-450 543 351)

The BIH Biomedical Innovation Academy office offers two online consultation hours via Microsoft Teams to clarify administrative and content-related questions about the call for proposals. The date and link to these events will be announced here.

Program Management

Dr. Nathalie Huber and Dr. Iwan Meij

BIH has commissioned the following project management organization to audit the use of funds in accordance with the Federal Budget Code:

DLR Projektträger
- Bereich Gesundheit -
Heinrich-Konen-Straße 1
53227 Bonn

7.1 APPLICATION DOCUMENTS AND USE OF THE ELECTRONIC APPLICATION SYSTEM

Applications are submitted online via the BIH Application and Reporting Portal.

The data protection information on the application and reporting procedure can be found here.

Further information and all application documents can be found here:

https://projekttraeger.dlr.de/de/foerderung/foerderangebote-und-programme/tandem-programm-gen-zelltherapie

All persons involved in the application and selection process (including the members of the independent expert jury) are subject to a confidentiality obligation.

7.2 SINGLE-STAGE APPLICATION PROCEDURE

The application procedure is single-stage. Applications are submitted online via the BIH Application and Reporting Portal and include the submission of applications that are complete in form and content and comply with the "Application Guideline/Hinweise zur Antragstellung" in electronic form.

Applications that do not meet the binding requirements set out therein may be rejected without further review.

Applications in electronic form must be submitted in the BIH Application and Reporting Portal

by November 07, 2024, 2 p.m.

at the latest.

7.3 TWO-STAGE SELECTION PROCEDURE

The submitted applications will undergo a two-stage selection procedure:

Stage 1 - Application review: The first stage involves the review of formally correct written applications by an independent jury of experts according to defined quality criteria and minimum standards.

The following will be assessed:

- the applicant institution(s) with regard to
  - fulfillment of the object of the funding (see chapter 2)
  - fulfillment of the funding requirements (see chapter 4)

- the tandem candidates with regard to
  - expertise
  - excellence
  - career potential and prospects

- the joint research project with regard to
  - the required translational character
  - clinical relevance
  - scientific and methodological quality and innovation potential
  - quality and scientific robustness of the preliminary work
  - feasibility of the project (appropriateness of milestones, work and time planning)

Stage 2 - Selection colloquium: The tandems rated highest by the expert jury will be given the opportunity to present themselves and their project in the second stage as part of a digital selection colloquium. The expected date of the selection colloquium can be found on the call for proposals website.

The institutions of the selected tandem candidates will then be notified of the results of the funding application and, if necessary, contacted regarding any outstanding formal regulations.

7.4 REGULATIONS TO BE OBSERVED

NOT TRANSLATED

7.5 NOTES

In the case of equal suitability and qualifications, special consideration is given to applications from severely disabled persons and persons with equivalent status. The aim is also to increase the proportion of women on the academic staff. In the case of equivalent qualifications, applications from female candidates are given priority as far as legally possible. Applications from candidates with a migration background who meet the recruitment requirements are expressly encouraged.

8. PERIOD OF VALIDITY

NOT TRANSLATED

Berlin, September 30th 2024

Berlin Institute of Health at Charité

On behalf of

Prof. Dr. Christopher Baum Dr. Doris Meder

ATTACHMENT

NOT TRANSLATED