

# National Project Funding of Gene- and Cell-Based Therapies



**GCT**

National Strategy  
Gene and Cell-Based Therapies  
**Project Funding**

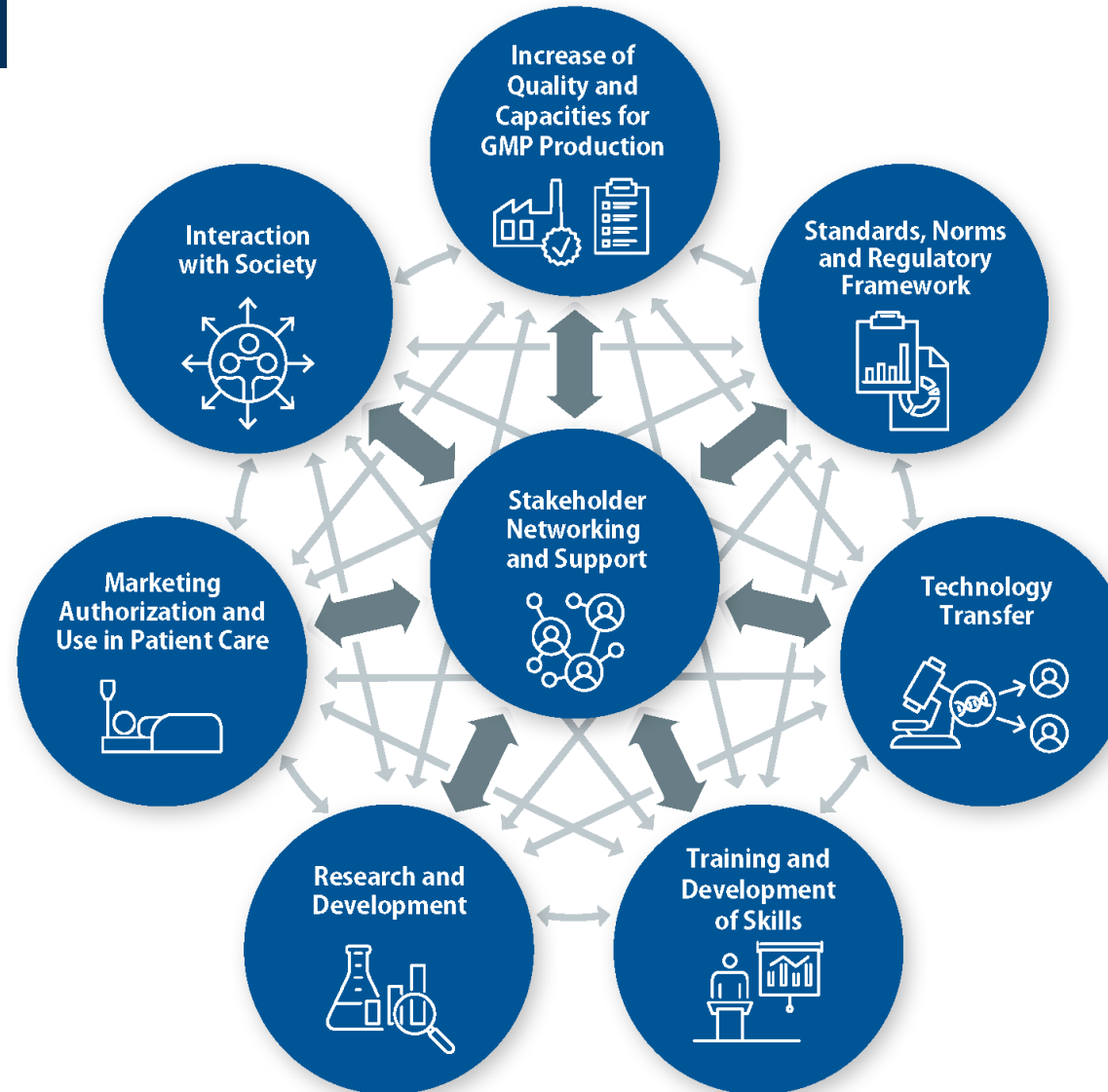
# National Strategy for Gene and Cell Therapies

## Background

- Aim of the National Strategy GCT
  - Improving patient access to gene and cell therapies and
  - Strengthening Germany as an international hub for research and innovation in this field
- BMBF commissioned BIH to coordinate and oversee the drafting of the strategy in a multi-stakeholder approach
- More than 150 experts from science, industry, public sector and society contributed to the formulation of concrete goals and measures to be implemented in eight action areas
- National Strategy was published on June 12, 2024  
[https://www.bihealth.org/fileadmin/GZT/NationaleStrategie\\_GCT\\_DE.pdf](https://www.bihealth.org/fileadmin/GZT/NationaleStrategie_GCT_DE.pdf)

# National Strategy for Gene and Cell Therapies

## The eight action areas



**GCT**

National Strategy  
Gene and Cell-Based Therapies  
Project Funding

# National funding of translational projects for gene and cell-based products and associated diagnostics – Second Call

Published 17.12.2024

# National funding of translational projects in Gene and Cell Therapy

## Rationale

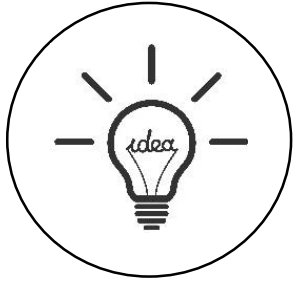
- Gene and cell therapies (GCTs) are a key technology driving innovation in biomedical research and patient care
- Potential to treat major diseases with targeted therapies tailored to the individual patient

## Aim

- Accelerate translation of findings from Germany's strong basic research programs into clinical practice
- Speed up and improve the translation of innovative GC therapies and associated diagnostics into marketable and clinically useful products and processes
- Creation of a strong GCT network in Germany

# National funding of translational projects in Gene and Cell Therapy

Aim: Support researchers and clinicians to advance their invention from laboratory to patient



✓ Funding +  
✓ Support



**PRODUCT or PROCESS**

## INVENTION

from any medical  
discipline for any  
disease entity

*IP requirements  
see next slide*

- Therapeutic approaches with ATMPs:
  - o Somatic cell therapeutics
  - o Gene therapeutics
  - o Tissue engineering products
- Therapeutic approaches with novel biological products, such as mRNA, extracellular vesicles or exosomes
- Diagnostic approaches, provided there is a clear link to GCT, in particular but not exclusively in the field of companion diagnostics.

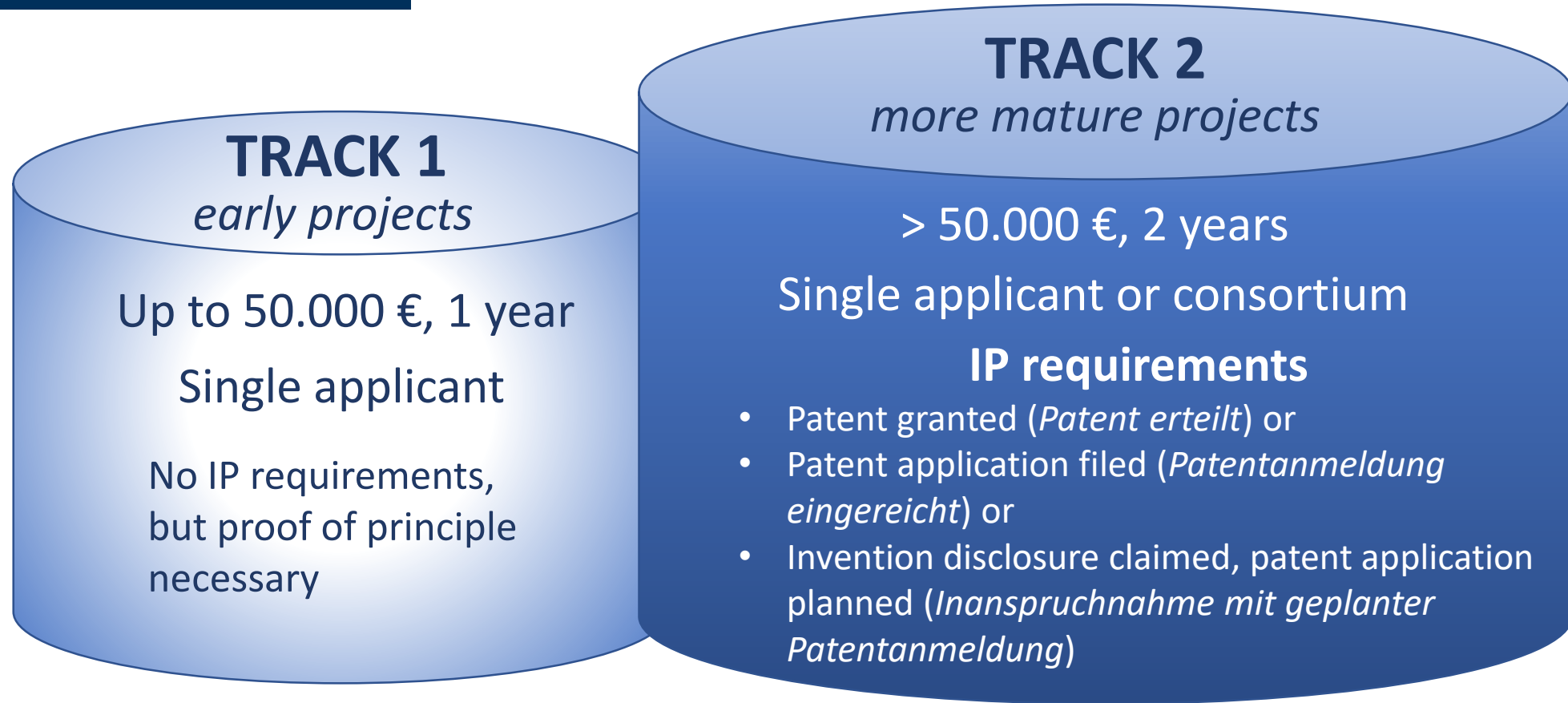


**GCT**

National Strategy  
Gene and Cell-Based Therapies  
**Project Funding**

# National funding of translational projects in Gene and Cell Therapy

## Funding in 2 Tracks



- **Majority of (planned) IP must be held by an academic institution**



**GCT**

National Strategy  
Gene and Cell-Based Therapies  
**Project Funding**

# Eligibility Criteria

## Applicants

- **Public and private universities** (single applicant, or coordinator or partner in research consortium)
- **Non-university research institutes** (partner in research consortium, only Track 2)
- **Enterprises** involved in health research and innovation (partner in research consortium, only Track 2)

## Budget restriction for non-university research institutes

- The budget of non-university research institutes must not exceed 50% of the total project budget
- The budget of non-university research institutes cannot be higher than that of other applicants



# Eligibility Criteria

## Project

- Translational, innovative, novel
- Based on already started product or process development
- Based on solid data (publication or preliminary results)
- Gene and Cell Therapy, associated diagnostics
- Any medical indication

## Product/process

- Addresses an unmet medical need
- Strong advantages compared to gold standard
- Competitive advantage
- High likelihood to reach patients / market

# National funding of translational projects in Gene and Cell Therapy

## Outcome

- Invention disclosure / patent
- Industry collaboration / licensing contract
- Follow-on funding (e.g. for clinical study)
- Start-up

# National funding of translational projects in Gene and Cell Therapy

## Potential work packages

- Planning and performing experiments necessary for translation
- Developing methods and processes necessary for translation
- Project-specific external advice, e.g. regulatory advice, market analysis
- Preclinical assessment of special product-specific properties addressing regulatory requirements
- Transfer to and optimisation of GMP production
- Developing and implementing quality criteria or standards
- Developing study protocols and informed consent forms for early clinical trials (Phase I/II)
- **NEW: Investigator-initiated clinical trials in phases I to IIb**
- Health Technology Assessments
- Measures for active patient involvement and involvement of other stakeholders

**NOTE Track 2:** Since funding can currently only be guaranteed until the end of 2026, please plan separate work packages for the year 2027.



**GCT**

National Strategy  
Gene and Cell-Based Therapies  
Project Funding

# National funding of translational projects in Gene and Cell Therapy

## What we offer

- Milestone-based funding
- Advice by an expert network
- Support by a team of project managers along the translational journey
- Becoming part of national GCT network and of SPARK global
- Education on translation and entrepreneurship
- Translational mindset – „think with the end in mind“

# National funding of translational projects in Gene and Cell Therapy

## Call procedure

- Submission deadline for project descriptions in English (PT Outline):  
**Track 1: February 17<sup>th</sup>, 2025, 13:00 (CET)**  
**Track 2: March 24<sup>th</sup>, 2025, 13:00 (CET)**
  - Project proposal (pdf) plus information in PT Outline
  - “Mustervorlage” has to be used for the proposal and instructions in the “Leitfaden” have to be followed
  - One project proposal for a consortium, **re-application possible**
- Submission deadline for formal project applications (easy online):  
**Track 1: March 24<sup>th</sup>, 2025**  
**Track 2: April 30<sup>th</sup>, 2025**
  - Formal project application consist of “Formantrag” (easy-Online) and a short German project description – template will be provided on the call webpage
  - For consortia, **each partner/institution** has to hand in
    - Formantrag including **declaration of a 10% share of the requested funding budget for applicants outside Berlin** and a short German description

# National funding of translational projects in Gene and Cell Therapy

## Call procedure

- Invitation for the presentation of selected Track 2 projects: **Beginning of June, 2025**
- Track 2 project presentations (Pitch Session): **June 30<sup>th</sup> - July 4<sup>th</sup>, 2025**
- Information of applicants on funding decision  
**Track 1: end of May, 2025**  
**Track 2: mid August, 2025**
- Project start:  
**Track 1: September, 2025**  
**Track 2: November, 2025**

# National funding of translational projects in Gene and Cell Therapy

## Selection Criteria

- Relevance to the aims and compliance with the requirements of the call
- Clinical relevance / unmet medical need
- Scientific and methodological quality, level of innovation
- Quality, validity and robustness of preliminary data
- IP status and marketability /exploitation strategy
- Feasibility of development within funding period (timeline, milestones, budget)
- Expertise of the team

# National funding of translational projects in Gene and Cell Therapy

## More information

- Visit us @ our websites

[Nationale Förderung von Translationsprojekten zur Therapie mit gen- und zellbasierten Produkten und assoziierter Diagnostik – zweite Förderbekanntmachung | DLR Projektträger](#)

- All relevant documents
- Available soon: Slides of the information meeting
- Available soon: FAQs
- Available soon: English versions

[SPARK-BIH Programm](#)

[https://www.bihealth.org/fileadmin/GZT/NationaleStrategie\\_GCT\\_DE.pdf](https://www.bihealth.org/fileadmin/GZT/NationaleStrategie_GCT_DE.pdf)

- Contact us for questions

Phone: +49 228 3821 1052

E-Mail: [Translation-GCT@dlr.de](mailto:Translation-GCT@dlr.de)