

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



**GCT**

National Strategy  
Gene and Cell-Based Therapies  
Project Funding

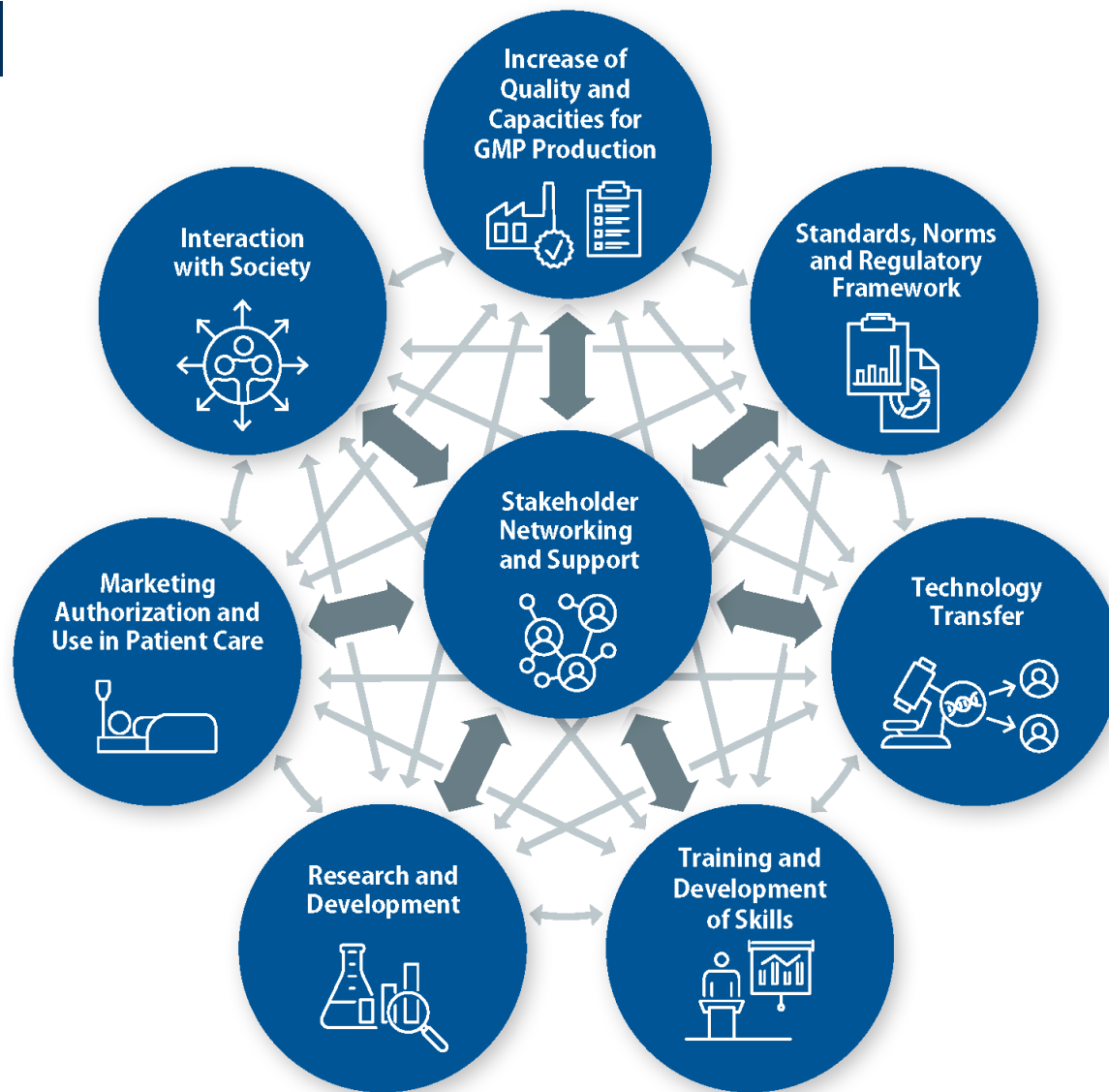
# National Strategy for Gene and Cell Therapies

## 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



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

Published 15.07.2024

# National funding of translational projects in Gene and Cell Therapy

## Rationale

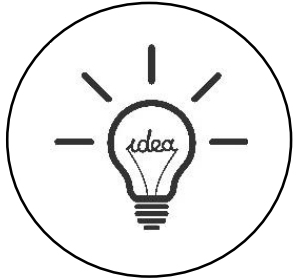
- Gene and cell therapies (GCTs) are a key technology driving innovation in biomedical research and patient care
- Potential to treat major diseases with targeted therapies tailored to the individual patient

## 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



## INVENTION

from any medical  
discipline

*IP requirements  
see slide 9*

✓ Funding +  
✓ Support



## PRODUCT or PROCESS

- 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.



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# Eligibility Criteria

## Applicants

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

## IP situation

- Majority of (planned) IP at an academic institution

# 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

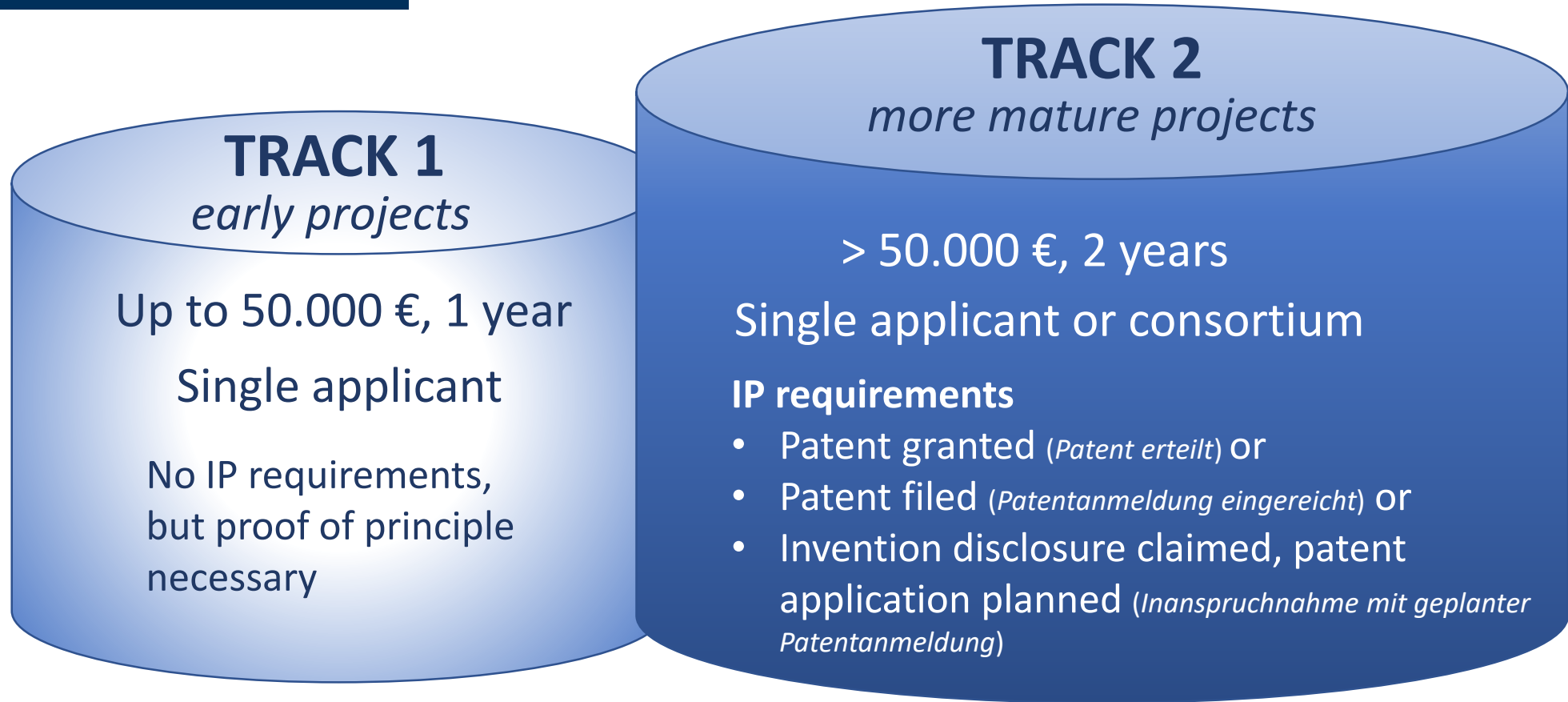
## Product/process

- Adresses 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

## Funding in 2 Tracks



# 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 research towards expected or already demanded conditions for regulatory approval, e.g. safety or efficiency studies
- Transfer to and optimisation of GMP production
- Developing and implementing quality criteria or standards
- Designing protocols for early clinical trials (Phase I/II) and informed consent forms
- Health Technology Assessments
- Measures for active patient involvement and involvement of other stakeholders

# 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): **August 27<sup>th</sup>, 2024, 13:00 (CEST)**
  - Project proposal (pdf) plus information in PT Outline (*portal opens August 1<sup>st</sup>*)
  - “Mustervorlage” has to be used for the proposal and instructions in the “Leitfaden” have to be followed
  - One project proposal for a consortium
- Submission deadline for formal project applications (easy online): **September 30<sup>th</sup>, 2024** and letter of intent for own contribution
  - 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 and short German description
    - Letter of intent (*Absichtserklärung zur Einbringung des Eigenanteils in Höhe von 10 % der in Zusammenhang mit dem Vorhaben stehenden finanziellen Aufwendungen*)
- Submission deadline for legally binding commitment for own contribution (each partner): **October, 30<sup>th</sup>, 2024** (*rechtsverbindlich von der antragstellenden Hochschule bzw. dem Sitzland unterzeichnete Erklärung zur Erbringung des Eigenanteils*)

# National funding of translational projects in Gene and Cell Therapy

## Call procedure

- Invitation for the presentation of selected Track 2 projects: **Beginning/ Middle of October, 2024**
- Track 2 project presentations (Pitch Session): **November 4<sup>th</sup> and 5<sup>th</sup>, 2024**
- Information of applicants on funding decision for Track 1 and Track 2 projects: **mid November 2024**
- Project start: **January 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  
<https://projekttraeger.dlr.de/de/foerderung/foerderangebote-und-programme/translationsprojekte-genzelltherapie>

### [SPARK-BIH Programm](#)

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

- Contact for questions

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