

IBT EXPLORE: ANNEX

Annex 1: Applications

The IBT Lower Saxony promotes the fastest possible transfer of research results into new preventive, diagnostic and therapeutic procedures. The IBT was initiated with the goal to boost innovations from Lower Saxony – accordingly, eligible for the current funding line are employees of institutions based in this federal state.

We are looking for:

- Promising ideas with prospects for scaling and commercialisation
- Innovative and research-based start-up projects
- Novel and valuable IP with high potential for further development

Funding for clearly defined modules with maximum 150.000 EUR in total is available for projects based in Lower Saxony. The final amount and modules will be awarded depending on the status, maturity and goals of the proposals, which will be reviewed externally in the selection process. The feasibility of the planning and the correspondingly requested funding will be reviewed as part of the selection process; therefore, we strongly encourage all prospective applicants to determine the amount of requested funding in a diligent and prudent manner based on actual needs. We reserve the right to award funding deviating from the requested sums or inclusion of Go/NoGo decision points following the review and recommendations by the Reviewers.

Eligible for funding are employees of academic institutions based in Lower Saxony. The project will be excluded from the procedure if:

- the project does not fit in the framework of the IBT's strategy and scope (e.g. no transfer project, no spin-off/start-up planned, project is below/above targeted project level range);
- the project representative(s) are not employees of an academic institution based in Lower Saxony;
- the project proposals are not signed off by the respective Transfer Office, Innovation Department, or a comparable unit within the hosting institution;
- the project goals are already funded by another source (double funding);
- funding from IBT is not necessary due to easy access to other types of funding;
- the patent(s) are not or will not be exclusively licensed to the planned spin-off;
- the project has already been spun out and incorporated as a business entity.

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Annex 2: Overview of project levels

Funding for drug discovery projects

The IBT will fund innovative new therapeutic concepts using small molecules, biologics (for example antibodies) or cell therapies for pharmaceutical intervention. They all require a clear understanding of the underlying biology of a disease; molecular targets for intervention should be verified. New therapeutic approaches should have a scientific rationale, a defined medical need and being superior versus standard of care (SoC).

Leaning on a calibration of maturity based on Technology Readiness Levels (TRL), there are four project levels (PL2-PL5¹) that the IBT considers for funding:

PL2	Screening and beyond At this level, the project must have a clearly defined concept with a path forward and modality defined to address a specific molecular target. This includes having screening assays in place, such as primary, secondary, tertiary assays, selectivity assays, and disease-relevant animal models for further proof of mechanism (PoM) and proof of concept (PoC). Go/No-Go decision criteria should be defined and a blueprint for the respective compounds created.
PL3	Lead identification; includes pharmacokinetics, in vivo, early ADMET and subsequent tests, preliminary biomarker plan At this level, the project has already completed screening and identified hit structures or molecules. Compound characterization and profiling assays are performed or ongoing to enable lead identification.
PL4	Further lead optimization and characterization; includes pharmacodynamics, ADMET safety tests, can the compound be produced for clinical studies, cost of goods At this level lead identification is completed (ideally more than one lead molecule identified) and the project is in the process for compound optimization (lead optimization) to identify a pre-candidate.
PL5	Preclinical studies; GLP, GMP, including production and formulation for Phase 1 studies The identified preclinical candidate needs further characterization.

¹ Project level 1 (PL1), i.e. fundamental science and open exploration of ideas, is currently not eligible for funding from the IBT Lower Saxony. All projects on PL2-PL5 must have a clear target product profile with proven validity.

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All other healthcare-related projects (technology/devices/digital)

The above outlined levels are valid only for drug discovery projects. However, the IBT may also support projects in which novel technologies including devices or digital solutions that are important for healthcare are pursued. These projects are likely in different development levels; below provide guidance on how to integrate them into the introduced project levels:

PL2	Identification of a medical need or vision and development of a solution strategy (device, technology or digital approach), understanding of the underlying concept, idea of a device/technology/digital product development, IP landscape and market/competitor and user demand analysis.
PL3	Preclinical device prototype/software/technology or a digital solution, animal testing of prototypes (if applicable), digital/technology test runs.
PL4	Refinement of prototype/software/technology with respect to market competition, potential revenues, feasibility, user demand, surveys of user satisfaction, strategy and partners for manufacturing the device.

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Annex 3: About the IBT funding

Framework

IBT funding supports the project purpose applied for and follows the financial plan proposed for this purpose. Deviations of more than 10% are only possible in consultation with IBT management. Cost-neutral extensions of the project duration are possible but also require the approval of IBT management. Any additional recommendations or restrictions by the Reviewers must be considered.

Use of the IBT funding

The total amount will be forwarded to the main applicant based in Lower Saxony, who will pass it on to other project partners on a pro rata basis as described in the financial plan. Staff costs are not eligible for funding. The proportion for services or other expenditure in the form of subcontracts can be determined flexibly depending on the needs of the project. As a default rule, subcontracts should be awarded via the institution of the main applicant; deviations from this are possible in consultation with the IBT management. Up to 20% of the scientific work can be realised by academic institutions outside Lower Saxony.

Service providers from Lower Saxony should be favored as long as the price difference to service providers outside Lower Saxony is not prohibitive. The awarding process must be carried out in accordance with the regulations of the respective organisation and documented for any verification of use. Contracts may only be awarded to service providers in non-European countries in consultation with IBT management.

Reporting obligations

Every 6 months using the relevant IBT templates (+ regular updates with IBT portfolio management during and beyond the funding period as required)

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Annex 4: Intellectual property requirement

In order to support successful commercialization of academic innovations and to ensure legal clarity and market exclusivity, all projects applying with the intention of founding a company must fulfill the following Intellectual Property (IP) requirements:

Exclusive rights to core IP

The applying project team must demonstrate that they hold or will secure exclusive rights—preferably in the form of an exclusive license—to all intellectual property (IP) that is critical to the intended business model, product, or service offering of the planned company. For all relevant patents and patent applications:

- Upon founding the startup, the applicant(s) must either own the patents or hold an exclusive license that allows them to use, develop, and commercialize the technology.
- The license must explicitly prohibit third parties from using or licensing the same IP in the same field of use, ensuring clear market exclusivity.

Freedom to operate

The applying project team should ascertain that the product will be free from third party rights by the time of launch. This includes:

- Freedom to operate analyses (the extent and content depending on the project status; before phase III, full FTO (product, manufacturing process, clinical formulation) should be done so that safe launch can be anticipated and major investments are justified)
- No conflicting licensing arrangements from the same institution
- No encumbrances or sublicenses that would restrict commercialization

Continued IP development

If further patents are anticipated, the applicant(s) must describe how future IP will be handled to maintain exclusivity and ensure alignment with the commercialization strategy.

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