NCT
NATIONALES CENTRUM
FÜR TUMORERKRANKUNGEN

# Continuous submission of trial synopses for funding within the NCT IIT Portfolio including the Overarching Clinical Translational Trial (OCT$^2$) Program

## Aims

The primary mission of the NCT is to conduct world-class innovative clinical translational research that aims to significantly improve the outcome and quality of life of cancer patients. The focus of this effort is to transfer promising preclinical research results into science-driven clinical multicenter trials with an emphasis on personalized oncology following a structured clinical translation process.

In order to achieve its mission, the NCT with its supporters offers continuous submission of trial synopses to fill the NCT IIT Portfolio. The major goals are:

- To perform IITs with NCT own proprietary compounds, treatment combinations or treatment concepts, as well as diagnostic and predictive tools or novel technologies from NCT own pipelines, usually from phase I to II (in selected cases also phase III).
- To address practice-changing questions in Phase II and III trials.
- To use - in a strategic and preferred manner - drug repositories combined with (pre-)clinical insights for a drug repurposing to be tested in clinical trials in the extended NCT.
- To activate clinical trials testing non-pharmaceutical interventions, e.g. in surgery, diagnostics, radiotherapy and psychooncological interventions.
- To strengthen the focus on patient-centered care by advancing and standardizing patient-reported outcome measures across NCT sites
- To use specific disease competence and synergies between the NCT sites that will create a much higher volume of recruitment in all types of trials.
- To increase the quality and speed of IITs by providing professional (infra)-structures at all sites as well as cross-site cooperation and harmonization.

## Funding

The NCT trial portfolio includes IITs fully funded by the NCT (OCT$^2$ program) and IITs receiving NCT support through infrastructures (e.g. CTCs). Participation of at least three NCT sites is mandatory to apply for funding.

Whenever possible, the structures and resources of the local CTCs should be used and external partners should only be contracted for CRO services in justified cases (i.e. services or specific expertise not covered by CTC). The principle of economic efficiency must be followed in all commissions of services.

In justified cases, costs incurred for the production of IMPs manufactured according to GMP guidelines (e.g. cellular immunotherapy or small molecule-based therapy) can be included in the total budget applied for. However, it should always be assessed whether additional or alternative resources are available.

All NCT-supported clinical trials are required to register and submit results information to the database ClinicalTrials.gov.

## Criteria

- Investigators from all partner sites of the NCT are eligible to apply. Proposals for IITs should describe clinically relevant, internationally competitive cutting-edge science including translational clinical studies, proof of concept clinical trials, and early innovative clinical diagnostic or intervention studies.
- Patient involvement must be ensured by active contribution of patient representatives in the development of the trial proposal. The active contribution must be documented by the main applicant.
- Expected benefit for the patients' perceived health status need to be considered and an assessment of patient-reported outcomes included in alliance with NCT principles and international measurement standards
- Studies legally sponsored by pharmaceutical industry or health technology companies will not be funded.
- If industrial representatives are involved in the study, investigational medical devices or investigational medicinal products must be provided by the industry partners. State Aid Rules must be considered and the Intellectual Property concept needs to be clear.
- In case of funding through the NCT OCT$^2$ Program the following regulations must be followed:
  - Biomaterials generated during the study must be provided to the local biobank of the NCT site and must be available to all participating partners for secondary use following the pertinent legal and biobank regulatory and approval processes.
  - Pseudonymized clinical and research data generated within the NCT-supported trials portfolio must be made available for secondary use to all NCT partner institutions following the pertinent legal and data governance regulatory and approval processes.
  - Before funding of the project starts, the conclusion of a cooperation agreement is necessary using the templates provided within the NCT cooperation agreement.

## Patient Involvement (NCT Patients as Research Partners)

- The development of the trial proposal must already contain active involvement of patient representatives. Active involvement must be proven by the main applicant.
- Patient involvement should be indication-specific whenever possible. That is, the patient representatives ideally should have expertise in the specific disease/trial population to be investigated.
- Patient representatives may come from the NCT sites, from patient-/self-help organizations, or can be individual patient representatives with relevant expertise. Depending on the trial/ trial population, contributors can be patients, relatives (e.g. parents) or patient advocates.
- The involvement of patient representatives should ideally range from being involved in the preparation of the synopsis (mandatory for submission of synopsis), in the detailed design of the trial, to actively supporting the trial itself (e.g. consulting, cooperation or monitoring).
- In section 2 under "patient involvement" in the web-portal please enter the following:
  - Name of patient representative(s) involved and, if applicable, the affiliation i.e. the NCT site, patient association or self-help organization.
  - List all activities in which the patient participant has been involved in the preparation of the trial synopsis so far. Also, please provide detailed information about the plans on how patient representatives will be involved in the suggested trial after approval. In addition to the conception and the design of the trial, this also applies to important factors improving the trial -

such as generation of knowledge, patient information, communication, dissemination, recruitment and anticipated impact on the patients' perceived health status.
  - Please indicate the amount of time (date and duration) each patient representative spent on meetings, phone calls, or other work related to the synopsis.
- The patient representatives in the NCT trials must be compensated for their time commitment. Initially from local NCT funds and, if the trial-project is successfully selected, from the trial budget.
- Please remember that finally every trial can also serve as a case study/case report for successful NCT patient involvement in cancer research. To document the successful collaboration between researchers/physicians and patients.
- The local NCT Patient Research Councils or the national NCT Patient Research Council (via the NCT Central Office) are available for further support. Please contact the coordinators of the respective NCT patient council as soon as a trial is planned – both if you are still looking for patient representatives and if you have already found them. He/she will support you regarding patient involvement including process and compensation.

## Modes and Duration of Funding

*Details in preparation*

## Evaluation Procedure

Applicants submit a trial synopsis in English via a web-portal (https://nct-trial-portal.dkfz.de). A user ID is required, which can be requested at https://nct-trial-portal.dkfz.de/user/id. The synopsis must provide a concise description of the trial and all information required to judge the quality and feasibility of the project. Detailed budget planning at submission is optional and can be developed or completed during the evaluation procedure.
After a formal pre-check of the completeness of the synopsis by the NCT Central Office (NCT CO) and a first check for serious concerns by the NCT Steering Committee, members of the NCT Trial Selection Board (NCT TSB) will evaluate the trial synopses on the basis of criteria such as medical need/significance for patients, international scientific competitiveness, preparatory work, innovation potential and contribution to the overall success of the NCT IIT Portfolio. The TSB will give a funding recommendation for prioritized proposals. Synopsis recommended for funding will undergo a regulatory check (CTO and other departments) and a medical feasibility review by the NCT Trial Monitoring Board (NCT TMB). A budget consultation is carried out by the CTO and the NCT CO together with the applicants. Feedback on the synopsis, with the opportunity to make adjustments if necessary, will be given at several stages of the process. Optionally, advice on the synopsis can be obtained through active participation in the PRT and PDA workshops (highly recommended). During the NCT TSB meetings, applicants will be invited to present the study synopsis and answer questions. The final decision on support/funding will be made by the NCT Steering Committee.

## Timelines

Continuous submission of proposals possible. NCT TSB meetings take place at least every 2 months

## Contact

NCT Central Office at German Cancer Research Center (DKFZ)

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