Continuous submission of study synopses for funding within the NCT-owned 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 starts the continuous submission of study protocols to fill the NCT-sponsored trial 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, and radiotherapy.
- 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.

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.
- 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 the 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 synopsis, in the detailed design of the study, to actively supporting the study/project itself (e.g. consulting, cooperation or monitoring).
- The patient representatives in the NCT studies must be compensated for their time commitment. Initially from general NCT funds and, if the trial-project is successfully selected, from the trial budget (part of the “Financial Summary”).
- In the template for the study synopsis "PROPOSAL - NCT IIT" please enter the following under heading 1 - field "Patient Involvement":
  - The name of patient representative(s) involved and the NCT site(s) or patient-/self-help organization(s).
  - Your common thoughts/plans on how patient representatives will be involved in the suggested trial. Not just in the conception and the design of the study, but possibly also in important factors to improve the trial - such as generation of knowledge, patient information, communication, dissemination, and recruitment or in other topics.
- Please remember that finally every trial project 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 Regional NCT Patient Research Councils or the National NCT Patient Research Council (via the NCT Central Office) are available for further support.

Modes and Duration of Funding

Details in preparation

Proposal Templates and 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 completed or developed during the evaluation procedure.

After a formal review of the completeness of the applications by the NCT Central Office (NCT CO) and the Clinical Trial Office (CTO), members of the NCT Trial Selection Board (NCT TSB) will evaluate the trial synopses and give a funding recommendation for prioritized proposals. Additionally, a regulatory check (NCT CO, CTO and other departments) and a medical feasibility review by the NCT Trial Monitoring Board (NCT TMB) takes place. Feedback on the application with the possibility for adjustments will be given, if needed, in several steps of the process. If necessary, applicants will be invited to present the trial synopsis or answer questions as part of a hearing within a meeting of the NCT TSB. The final decision on support/funding is made by the NCT Steering Committee.

Timelines

Q2 2023	Start of continuous submission of proposals
From Q4/2023	NCT TSB selects trials once in a quarter

Contact

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