NCT
NATIONALES CENTRUM
FÜR TUMORERKRANKUNGEN

NCT Clinical and Medical Trialist (CMT) Program

Purpose and target groups

A central goal of the NCT is to promote and expand career paths in translational and clinical cancer research. The NCT Clinical and Medical Trialist (CMT) program provides attractive opportunities for highly motivated physicians (e.g. clinician scientists) and translation-oriented researchers (medical scientists), who wish to become experts in the design and implementation of clinical trials and translational research in the field of oncology. The conception, initiation and execution of a clinical trial requires a broad range of expertise next to medical knowledge, including competencies such as knowledge in biostatistics, ethics and regulatory affairs as well as experience in project management and team building, budgeting and acquisition of third-party funding. Furthermore, collaboration with patient representatives and study personnel plays a key role, especially within the NCT, in effectively planning and designing innovative clinical trials in oncology.

Within a structured curriculum, participants engage in different learning formats such as workshops, seminars, and an annual one-week training course (NCT Masterclass) dedicated to the development and refinement of their clinical trial protocols. This curriculum will train the participants as CMTs with a defined track for career development (e.g. senior consultant or senior medical trialist in academia, clinical trials organizations or industry). Participants in the program will be actively involved in clinical trials in the One NCT and, supported by the curricular activities, will design their own trial and translational research idea. The curriculum will further include specific aspects of biomarker development, innovative imaging technologies, robotics, artificial intelligence and/or bioethical issues and reverse translation. CMTs will be encouraged to submit clinical study proposals for funding by the NCT Overarching Clinical Translational Trial (OCT[2]) program or the most appropriate third party.

Upon completion of the program, participants will be able to design clinical trials, prepare study protocols, and submit applications for their implementation in a scientifically sound and formally correct manner. Participants will receive a certificate upon completion of the CMT program[1].

Structure and content

The program imparts core competencies in clinical studies covering the full trial lifecycle from study design and endpoints (e.g. adaptive trials, real-world data) to quality assurance (e.g. SAE/SUSAR management, monitoring), biostatistics (e.g. sample size calculation), and regulatory aspects (e.g. ethics committees, AMNOG, EMA/FDA, GDPR).

It is complemented by overarching professional skills such as project management, funding strategies, scientific communication, and leadership, as well as specialized modules (e.g. AI in clinical research, immuno- and cell-based therapies, drug design). Mentoring, networking, and One NCT formats (e.g. Masterclass, Community Retreat, NCT Workshops für Priority Disease Areas und Priority Research Themes und SCCR Seminar Series) support career development including career planning and cross-site collaboration[2].

[1] Participants receive funding for up to two years and are offered to attend training modules for core competences and additional training modules on demand. Participants must complete at least 80% of the core curriculum.
[2] Detailed curriculum attached

Eligibility and selection process

CMTs are recruited locally through a competitive process based on the nationally established criteria for NCT Clinical Trialists (see Table 1) and NCT Medical Trialists (see Table 2). Applicants are encouraged to submit a description of their own clinical study concept as part of the application; however, this is not a mandatory requirement. The requirements, selection criteria, and objectives/tasks for the respective target groups are outlined in the middle and right-hand columns of the tables.

Local calls for applications are announced at least annually and advertised both locally and across the One NCT. The recruitment process is overseen by the corresponding local NCT Education and Training Committee.

Table 1: Criteria NCT Clinical Trialists | Short-term 12 months or long-term up to 24 months, 25–50% protected time for scientific activities within the framework of clinical trials. Release from duties for the proposed project must be confirmed in writing by the supervising person or institution; cross-financing from existing funds is excluded.

Prerequisites	Selection criteria (facultative)	Objectives / Responsibilities
• Medical license; doctoral degree recommended • Basic GCP course • Ability to write scientific texts, study protocols, or third-party funding applications in English • Interest in a career with a focus on the conception and conduct of clinical trials	• Experience as a member of national/ international trial or study groups or working groups • Concept outline of a study idea • Prior knowledge of study design • Scientific track record (publications, grants) • Ability to work in a team and high level of commitment	• Regular participation in the curriculum, including qualification to lead an investigator group (certificate upon completion) • Development of study designs and integration of biostatistics • Preparation of study protocols • Submission of studies for funding within the OCT² program • Collaboration with experts in translational research • Interaction within One NCT • Peer mentoring • Regular interaction with two mentors (one local, one external)

Table 2: Criteria NCT Medical Trialists | Short-term 12 months or long-term up to 24 months, 25–50% protected time for scientific activities within the framework of clinical trials. Release from duties for the proposed project must be confirmed in writing by the supervising person or institution; cross-financing from existing funds is excluded.

Prerequisites	Selection criteria (facultative)	Objectives / Responsibilities
• Completed Master's degree / State Examination (e.g. in life and social sciences such as biomedicine, biology, pharmacy, biostatistics, psychology, sociology, physics, or engineering); doctoral degree desirable • Ability to prepare scientific texts and/or third-party funding applications in English • Experience with scientific projects in the context of clinical trials or interest in such a focus • Research idea with scientific alignment to existing or planned NCT OCT² studies	• Experience as a member of national/international investigator or study groups or working groups • Experience in the conduct or operational support of clinical trials • Prior knowledge in study design: development of study concept and integration of biostatistical, natural science, psychological, pharmaceutical, sociological, etc. components • Scientific track record (publications, grants) • Ability to work in a team and high level of commitment	• Regular participation in the curriculum, including qualification to lead an investigator group (certificate upon completion) • Development of study designs with integration of accompanying research • Active participation in the submission of study concepts for funding within the OCT² program • Collaboration with experts in the field of translational research • Interaction within One NCT • Peer mentoring • Regular interaction with two mentors (one local / one external)

Contact

For further inquiries, please contact your local NCT coordination site (open calls) and/or the coordination of the School of Clinical Cancer Research (general information, nct-sccr@dkfz.de).

NCT CMT Curriculum

Core Curriculum

Fundamentals of Clinical trials

- Trial development (Defining unmet clinical needs, New / adaptive study designs, Defining and implementing appropriate study endpoints, Protocol writing / preparation of documents, Logistics/ budget planning, Clinical data management / eCRF / EDC systems, Real-world data, Register, secondary use of data)
- Quality assurance in clinical trials (SAE/SUSAR Management, Pharmacovigilance, Monitoring, Audits, Inspections, Risk-based monitoring)
- Patient involvement and communication (PRO, shared decision making, informed consent)
- Legal and regulatory aspects (Interaction with ethics commission and national and federal state authorities, European/international perspectives, Early benefit assessment [AMNOG, G-BA, EMA/FDA interactions], General Data Protection Regulation [GDPR])
- Biostatistics (Basics in e.g. sample size calculation, statistical models)

Key Professional Competencies

- Project management (milestones, resources, risk management, consortium coordination)
- Financing options (contract research/ funding institutions)
- Media skills (Presentation techniques, Scientific writing, Publishing trial results, Science Communication)
- Business Basics (HR management in the context of clinical trials/ team, leadership, conflict management)
- Business Advanced (Spin-offs, IP, patents, entrepreneurship)

Mentoring and NCT-specific interactions

- Career planning
- Networking at national and international congresses
- Mentoring (senior mentoring by experienced trialists as well as peer mentoring among fellows at the same or similar career stage)

One NCT events

- NCT Masterclass and/or Annual NCT Community Retreat
- Exchange rotation(s) between NCT sites
- Regular webinars covering topics such as use cases and success stories from One NCT as well as career prospects of CMTs
- NCT workshops for PDAs and PRTs

Additional Modules on demand

- AI in clinical research (imaging, pathology, trial optimization, decision support)
- Ancillary studies, biobanking, reverse translation
- Drug design: small molecules and therapeutic antibodies
- *In vivo* pharmacodynamics and pharmacokinetics
- Immunotherapy / cell-based therapies/ATMPs
- Translational preclinical development of bispecific antibodies (BsAbs) as well as CAR-T cells and adapter CAR-T cells
- Theranostics

- Clinical research in precision oncology
- Clinical research in surgical oncology
- Clinical research in radiation oncology
- Clinical research in diagnostics (pathology, imaging …)