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 …)