Topics Clinical Research Training

Topics	Key issues
Regulation International	• Overview: Introduction to clinical research • Worldwide ethical and regulatory framework (in combination with national regulations, if requested) • History of clinical research ethics • Good Clinical Practice, GCP • Declaration of Helsinki, other legal regulations on ethics • European regulation • Regulatory submission • Medical device studies • Legal specifics: Clinical trials - with participants < age of 18, - in intensive / emergency medicine - including gene therapy • Good Laboratory Practice, GLP
Regulations / Submission Processes National (National Authorities and Ethics Committees)	• China, including - China-specific GCP regulations - drug- and medical device development process • Germany • Swiss • Turkey • (Other associated ICN members)

Study Design	• One day training: Clinical study design (I) and (II) • Clinical study design short • Drug development process • Clinical phases • Interventional and observational clinical research • Different designs for special population / fields (rare diseases, pediatrics, etc.)

Roles and Responsibilities	• Sponsor • Investigator (and site staff) • Further clinical research team at site • Clinical trial manager • Clinical research organizations (academic-commercial) • Ethics committee (structure, role, approval processes, benefit/risk rationale, participant rights, evaluation of IC, etc.) • Third parties (pharmacy, radiology, pathology, core lab, etc.)
Study Documents	• Protocol: Conception - writing • Informed consent (IC), General consent: History – conception • Case report forms • Investigators brochure • Feasibility questionnaire • TMF - ISF • Standard Operating Procedures (SOPs) • Conflict of interest
Trial Planning - Start-up Activities	• Preparation of study documents (CSP, IC, CRF, TMF, others) • Country selection - Site selection • Site feasibility • How to apply for funding / research grants • Set up of clinical trial budget • Site budget and site contract
Trial Initiation	• Site initiation • Documentation, data entry in CRF • Investigational Medical Product (IMP) management
Trial Conduct	• Patient screening and inclusion • Patient recruitment systems and strategies • Clinical operations • Protocol compliance: Deviations, violations, note to files • Financial management

Trial Close Out	• Close out activities and archiving

Clinical Trial Management	• Overview clinical trial management
Statistics and Biometry	• Basic concepts of statistics • Methodology to avoid bias (controlled trials, randomization, blinding) • Statistical planning and analysis • Bioinformatics • Randomization tools
Data management	• Data management –overview • Electronic data capture (EDC): Software requirements, operation, central elements, software examples (SecuTrial, MACRO, REDCap) • System validation process of GCP-compliant software systems • CRF: Development, getting from the protocol to the final CRF • Randomization • Data collection, query management, validation processes
Quality Control and Monitoring	• Quality and risk management system - basic principles, SOPs, further documents - requirements, development, maintenance • Sponsor´s responsibility: Audits • Regulatory Authority: Inspections • Monitoring principles • Selection /responsibilities of monitor (clinical research associate, CRA)
Safety	• Safety principles • Adverse event reporting • Safety reporting responsibilities of the Sponsor
Reporting	• Medical writing in clinical trials

Translational Research	• Translational research – regulatory aspects, logistic challenges • Biobank systems • How to build up a biobank
Other Issues	• How to set up an academic “Clinical Trial Center” • Data exchange among different countries • Clinical research terminology