

Module title		Abbreviation
Clinical Studies (GCP, AMG, MPG)		03-TM-KLST-181-m01
Module coordinator		Module offered by
Institute of Clinical Epidemiology and Biometry (ICE-B)		Faculty of Medicine
ECTS	Method of grading	Only after succ. compl. of module(s)
5	numerical grade	--
Duration	Module level	Other prerequisites
1 semester	graduate	--
Contents		
Design and implementation of clinical trials; conduct of clinical trials according to ethical and legal requirements.		
Intended learning outcomes		
The students are faced practical issues of the development and implementation of study designs. They acquire knowledge in protocol development, trial documents, ethical issues, patient information, data management and establishing trial procedures in multi-center studies. They learn about trial conduct in accordance with Good Clinical Practice and legal requirements (drug law, medical product law). The course for investigators visited within this setting allows participating physicians to act as trial investigators. Seminars serve to develop knowledge to practical abilities using examples from the real study world. In addition, the students will acquire special knowledge about design aspects, e.g., sample size calculation.		
Courses (type, number of weekly contact hours, language – if other than German)		
V (1) + S (1) Module taught in: German or English		
Method of assessment (type, scope, language – if other than German, examination offered – if not every semester, information on whether module is creditable for bonus)		
oral examination (approx. 30 minutes) Language of assessment: German or English		
Allocation of places		
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Additional information		
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Workload		
150 h		
Teaching cycle		
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Referred to in LPO I (examination regulations for teaching-degree programmes)		
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Module appears in		
Supplementary course Translational Medicine (2018) Master's degree (1 major) Translational Medicine (2018)		