**Module title**  
Clinical Studies (GCP, AMG, MPG)

**Abbreviation**  
03-TM-KLST-181-m01

**Module coordinator**  
Institute of Clinical Epidemiology and Biometry (ICE-B)

**Module offered by**  
Faculty of Medicine

**ECTS**  
5

**Method of grading**  
Numerical grade

**Duration**  
1 semester

**Module level**  
Graduate

**Other prerequisites**  
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### Contents

Design and implementation of clinical trials; conduct of clinical trials according to ethical and legal requirements.

### Intended learning outcomes

The students are faced with 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

**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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### 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)