



INSTITUTIONEN FÖR MEDICIN

MED563 Klinisk prövning, 7,5 högskolepoäng

Clinical Trials in Medicine, 7.5 credits

Avancerad nivå / Second Cycle

Litteraturlista för MED563, gällande från och med höstterminen 2021

.

Se bilaga.

MED563 Clinical Trials in Medicine, 7,5 högskolepoäng

- Textbook "Fundamentals of Clinical Trials", Springer 5th Edition, Lawrence M. Friedman", Curt D. Furberg, Davis L. DeMets
 - Chapter 1 "Introduction to Clinical Trials"
 - Chapter 2 "Ethical Issues"
 - Chapter 3 "What is the Question?"
 - Chapter 4 "Study Population"
 - Chapter 5 "Basic Study Design"
 - Chapter 8 "Sample Size"
 - Chapter 12 "Assessment and Reporting of Harm"
 - Chapter 14 "Participant Adherence"
 - Chapter 15 "Survival Analysis"
 - Chapter 21 "Multicenter Trials"
- Clinical investigation of medical devices for human subjects-Good clinical practice (ISO 14155:2011)
- Declaration of Helsinki (revised Brazil, October 2013)
- EU Directives, 2001/20/EC and 2005/28/EC (Pharmaceuticals).
- EU Directives: 98/79/EC and 2007/47/EC (Medical Devices).
- ICH Topic E6: Guideline for Good Clinical Practice (CPMP/ICH/135/95)
- ICH Topic E 8: General Considerations for Clinical Trials (CPMP/ICH/291/9)
- ICH Topic E 9: Statistical Principles for Clinical Trials (CPMP/ICH/363/96)
- ICH Topic E 10: Choice of Control Group in Clinical Trials
- Webpages
 - www.clinicaltrials.gov
 - www.clinicaltrialsregister.eu
 - <http://ec.europa.eu/health/documents/eudralex/vol-10/>
 - http://ec.europa.eu/health/files/eudralex/vol-4/2009_06_annex13.pdf
 - http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2013/06/WC500144469.pdf
- Presentation materials in the form of videos, audio files and slides.