UCLouvain

wmphm2203

2026

Clinical trials and vaccine development studies (UCLouvain)

2.00 credits	12.0 h + 8.0 h	Q2

Teacher(s)	Sawadogo Kiswendsida Clovis ;
Language :	English
Place of the course	Bruxelles Woluwe
Learning outcomes	
Evaluation methods	A two-part written examination: one part covering theoretical questions relating to the concepts covered in the course, and the other consisting of practical exercises using statistical software, as practised during the practical sessions. Decimals will be rounded down to the nearest whole number. AI may be used as a revision aid and support tool, but is not permitted during the final assessment.
Teaching methods	Learning will take place · through face-to-face lectures illustrated with real-life examples · through practical exercises.
Content	**Contents** I. Clinical trials I.1 Basics & Principles I.2 Trials methodology I.3 Clinical Phase I (first-in-man trial) I.4 Clinical Phase II (first-in-patient trial) I.5 Clinical Phase III (evidence trial) II. Survival analysis II.1 Fundamental concepts II.2 Survival and hazard II.3 Kaplan-Meier estimate II.4 Log-rank test II.5 Cox regression II.6 Sample size for a survival study
Inline resources	The course slides and reference materials are available on Moodle
Bibliography	Eric Vittinghoff • David V. Glidden • Stephen C. Shiboski • Charles E. McCulloch. **Regression Methods in Biostatistics** . Linear, Logistic, **Survival** , and Repeated Measures Models. Springer, 2012 (2nd Edition) **(Pages 54-62)** Zeng M, Mao XH, Li JX, Tong WD, Wang B, Zhang YJ, Guo G, Zhao ZJ, Li L, Wu DL, Lu DS, Tan ZM, Liang HY, Wu C, Li DH, Luo P, Zeng H, Zhang WJ, Zhang JY, Guo BT, Zhu FC, Zou QM. Efficacy, safety, and immunogenicity of an oral recombinant Helicobacter pylori vaccine in children in China: a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet. 2015 Oct 10;386(10002):1457-64. doi: 10.1016/S0140-6736(15)60310-5. Epub 2015 Jun 30. PMID: 26142048.
Faculty or entity in charge	FSP