









5 credits

22.5 h + 7.5 h

Q2

Teacher(s)	Legrand Catherine ;Robert Annie ;
Language :	French
Place of the course	Louvain-la-Neuve
Main themes	The following topics will be discussed: - International guidelines in clinical trials. - Phase 1: pharmacokinetics and pharmacodynamics. - Phase 1: dose determination: the continual reassessment method. - Phases 2 & 3: hypothesis tests in efficacy, superiority or equivalence trials. - Phases 2 & 3: power and sample size computation, randomisation and blinding. Application to sequential trials. - Phases 2 & 3: cross-over and factorial designs. - Phase 4: pharmacovigilance. Rare events and risk factors. - Reporting in clinical trials.
Aims	<p>1 Objectives The goal of this course is to propose a broad overview of the statistical aspects of phase 1, 2, 3 and 4 clinical trials.</p> <p>-----</p> <p><i>The contribution of this Teaching Unit to the development and command of the skills and learning outcomes of the programme(s) can be accessed at the end of this sheet, in the section entitled "Programmes/courses offering this Teaching Unit".</i></p>
Content	The following topics will be discussed: - International guidelines in clinical trials. - Phase 1: pharmacokinetics and pharmacodynamics. - Phase 1: dose determination: the continual reassessment method. - Phases 2 & 3: hypothesis tests in efficacy, superiority or equivalence trials. - Phases 2 & 3: power and sample size computation, randomisation and blinding. Application to sequential trials. - Phases 2 & 3: cross-over and factorial designs. - Phase 4: pharmacovigilance. Rare events and risk factors. - Reporting in clinical trials.
Other infos	References : Redmond, C. K. and Colton T. (2001), Biostatistics ub Clinical Trials, Wiley. Fleiss J. (1986), The Design and Analysis of Clinical Experiments. Wiley.
Faculty or entity in charge	LSBA

Programmes containing this learning unit (UE)				
Program title	Acronym	Credits	Prerequisite	Aims
Master [120] in Biomedical Engineering	GBIO2M	5		
Master [120] in Statistics: General	STAT2M	5		
Master [60] in Biomedicine	SBIM2M1	5		
Master [120] in Mathematical Engineering	MAP2M	5		
Master [120] in Mathematics	MATH2M	5		
Master [120] in Biomedicine	SBIM2M	5		
Master [120] in Statistics: Biostatistics	BSTA2M	5		
Minor in Statistics and data sciences	LSTAT100I	5		
Additional module in Statistics and data science	LSTAT100P	5		