UCLouvain

lstat2330

2022

Statistics in clinical trials.

5.00 credits	22.5 h + 7.5 h	Q2

Teacher(s)	Legrand Catherine ;Robert Annie ;
Language :	French
Place of the course	Louvain-la-Neuve
Prerequisites	Concepts and tools equivalent to those taught in teaching units LSTAT2014 Eléments de probabilités et de statistique mathématique LSTAT2120 Linear models
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.
Learning outcomes	**At the end of this learning unit, the student is able to :** 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.
Evaluation methods	Closed-book written exam. Depending on the evolution of the situation, the written exam could be replaced by a closed-book oral exam organised remotely.
Teaching methods	The course consists of lectures and discussion of documents distributed during the course. Practical works are also organised. They aim to: - deepen concepts introduced during the course, - analyse real data using tools presented during the course. Depending on the evolution of the situation, the course will be given either in presential or remotely.
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.
Inline resources	All necessary resources will be made available via Moodle.
Bibliography	Redmond, C. K. and Colton T. (2001), Biostatistics ub Clinical Trials, Wiley. Fleiss J. (1986), The Design and Analysis of Clinical Experiments. Wiley.
Other infos	Prerequisites: Bases of probability and descriptive and inferential statistics, basic knowledge of SAS and R.
Faculty or entity in charge	LSBA

Programmes containing this learning unit (UE)

Program title	Acronym	Credits	Prerequisite	Learning outcomes
Master [120] in Biomedicine	SBIM2M	3		
Master [120] in Biomedical Engineering	GBIO2M	5		
Master [120] in Statistics: Biostatistics	BSTA2M	5		
Master [60] in Biomedicine	SBIM2M1	3		
Master [120] in Mathematics	MATH2M	5		
Master [120] in Statistics: General	STAT2M	5		
Master [120] in Chemistry and Bioindustries	BIRC2M	5		
Approfondissement en statistique et sciences des données	APPSTAT	5		
Master [120] in Mathematical Engineering	MAP2M	5		
Mineure en statistique et science des données	MINDATA	5		
Minor in Statistics, Actuarial Sciences and Data Sciences	MINSTAT	5		
Certificat d'université : Statistique et science des données (15/30 crédits)	STAT2FC	5		
Master [120] in Agricultural Bioengineering	BIRA2M	5		