UCLouvain

lstat2330

2020

Statistics in clinical trials.

Due to the COVID-19 crisis, the information below is subject to change, in particular that concerning the teaching mode (presential, distance or in a comodal or hybrid format).

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	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. - - - - *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".*
Evaluation methods	**Due to the COVID-19 crisis, the information in this section is particularly likely to change.** 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	**Due to the COVID-19 crisis, the information in this section is particularly likely to change.** 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	Aims
Master [120] in Mathematics	MATH2M	5		
Mineure en statistique et science des données	MINDATA	5		
Master [120] in Biomedicine	SBIM2M	3		
Certificat d'université : Statistique et sciences des données (15/30 crédits)	STAT2FC	5		
Minor in Statistics, Actuarial Sciences and Data Sciences	MINSTAT	5		
Master [120] in Mathematical Engineering	MAP2M	5		
Master [60] in Biomedicine	SBIM2M1	3		
Master [120] in Agricultural Bioengineering	BIRA2M	5		
Master [120] in Chemistry and Bioindustries	BIRC2M	5		
Approfondissement en statistique et sciences des données	APPSTAT	5		
Master [120] in Statistic: General	STAT2M	5		
Master [120] in Statistic: Biostatistics	BSTA2M	5		
Master [120] in Biomedical Engineering	GBIO2M	5		