

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
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	<p><b>At the end of this learning unit, the student is able to :</b></p> <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>
Evaluation methods	<p>Closed-book written exam.</p> <p>Depending on the evolution of the situation, the written exam could be replaced by a closed-book oral exam organised remotely.</p>
Teaching methods	<p>The course consists of lectures and discussion of documents distributed during the course.</p> <p>Practical works are also organised. They aim to: - deepen concepts introduced during the course, - analyse real data using tools presented during the course.</p> <p>Depending on the evolution of the situation, the course will be given either in presential or remotely.</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.
Inline resources	All necessary resources will be made available via Moodle.
Bibliography	<p>Redmond, C. K. and Colton T. (2001), Biostatistics ub Clinical Trials, Wiley.</p> <p>Fleiss J. (1986), The Design and Analysis of Clinical Experiments. Wiley.</p>
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 Statistics: General	<a href="#">STAT2M</a>	5		
Master [120] in Agricultural Bioengineering	<a href="#">BIRA2M</a>	5		
Master [60] in Biomedicine	<a href="#">SBIM2M1</a>	3		
Master [120] in Mathematics	<a href="#">MATH2M</a>	5		
Mineure en statistique et science des données	<a href="#">MINDATA</a>	5		
Master [120] in Statistics: Biostatistics	<a href="#">BSTA2M</a>	5		
Master [120] in Biomedical Engineering	<a href="#">GBIO2M</a>	5		
Master [120] in Biomedicine	<a href="#">SBIM2M</a>	3		
Approfondissement en statistique et sciences des données	<a href="#">APPSTAT</a>	5		
Minor in Statistics, Actuarial Sciences and Data Sciences	<a href="#">MINSTAT</a>	5		
Master [120] in Chemistry and Bioindustries	<a href="#">BIRC2M</a>	5		
Certificat d'université : Statistique et sciences des données (15/30 crédits)	<a href="#">STAT2FC</a>	5		
Master [120] in Mathematical Engineering	<a href="#">MAP2M</a>	5		