











In view of the health context linked to the spread of the coronavirus, the methods of organisation and evaluation of the learning units could be adapted in different situations; these possible new methods have been - or will be - communicated by the teachers to the students.

5 credits	22.5 h + 7.5 h	Q2
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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.
Bibliography	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
Mineure en statistique et science des données	<a href="#">LOSTA100I</a>	5		
Approfondissement en statistique et sciences des données	<a href="#">LSTAT100P</a>	5		
Minor in Statistics, Actuarial Sciences and Data Sciences	<a href="#">LSTAT100I</a>	5		
Master [120] in Biomedical Engineering	<a href="#">GBIO2M</a>	5		
Master [120] in Mathematical Engineering	<a href="#">MAP2M</a>	5		
Master [120] in Statistic: Biostatistics	<a href="#">BSTA2M</a>	5		
Certificat d'université : Statistique et sciences des données (15/30 crédits)	<a href="#">STAT2FC</a>	5		
Master [120] in Mathematics	<a href="#">MATH2M</a>	5		
Master [120] in Biomedicine	<a href="#">SBIM2M</a>	3		
Master [120] in Statistic: General	<a href="#">STAT2M</a>	5		
Master [60] in Biomedicine	<a href="#">SBIM2M1</a>	3		