LSTAT2330

2015-2016

Statistics in clinical trials.

5.0 credits	22.5 h + 7.5 h	2q

Teacher(s) :	Legrand Catherine ; Robert Annie ;
Language :	Français
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 :	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".*
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 / formations proposant cette unité d'enseignement (UE)				
Intitulé du programme	Sigle	Credits	Prerequis	Acquis d'apprentissage
	STAT9CE	5	-	
Master [120] in Statistics: Biostatistics	BSTA2M	5	-	
Master [120] in Statistics: General	STAT2M	5	-	
Master [120] in Mathematics	MATH2M	5	-	
Master [120] in Biomedical Engineering	GBIO2M	5	-	
Master [120] in Biomedicine	SBIM2M	3	-	
Master [60] in Biomedicine	SBIM2M1	3	-	
	STAT2FC	5	-	