

**STAT**

STAT2530 Statistics in clinical trials.

[22.5h+7.5h exercises] 5 credits

This course is taught in the 2nd semester

**Teacher(s):** Philippe Lambert, Annie Robert  
**Language:** french  
**Level:** 2nd cycle course

**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.

**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.

**Content and teaching methods**

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 information (prerequisite, evaluation (assessment methods), course materials recommended readings, ...)**

## References :

Redmond, C. K. and Colton T. (2001), Biostatistics ub Clinical Trials, Wiley.  
Fleiss J. (1986), The Design and Analysis of Clinical Experiments. Wiley.

For more information:

<http://www.stat.ucl.ac.be/cours/stat2530/index.html> <http://www.stat.ucl.ac.be/cours/stat2530/index.html>

**Other credits in programs**

<b>ESP31DS/DM</b>	Première année du diplôme d'études spécialisées en santé publique (gestion des données médicales)	(5 credits)	
<b>ESP3DS/EP</b>	Diplôme d'études spécialisées en santé publique (recherche clinique)	(5 credits)	
<b>MATH22/S</b>	Deuxième licence en sciences mathématiques (Statistique)	(3 credits)	
<b>SBIC22</b>	Deuxième licence en sciences biomédicales (sciences biomédicales cliniques)		Mandatory
<b>STAT2MS</b>	Master en statistique, orientation générale, à finalité spécialisée	(5 credits)	
<b>STAT3DA/B</b>	diplôme d'études approfondies en statistique (biostatistique et épidémiologie)	(5 credits)	Mandatory
<b>STAT3DA/P</b>	diplôme d'études approfondies en statistique (pratique de la statistique)	(5 credits)	