

Institute of Statistics



STAT2530 Statistics in clinical trials.

[22.5h+7.5h exercises] 5 credits

This course is taught in the 2nd semester

Teacher(s): Annie Robert
Language: French
Level: Second cycle

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

SBIC22	Deuxième licence en sciences biomédicales (sciences biomédicales cliniques)	Mandatory
STAT21MS/ST	Première année du master en statistique, orientation générale, à finalité spécialisée (sciences et technologie) (5 credits)	
STAT22MS/ST	Deuxième année du master en statistique, orientation générale, à finalité spécialisée (sciences et technologie) (5 credits)	
STAT3DA/B	diplôme d'études approfondies en statistique (biostatistique et épidémiologie) (5 credits)	Mandatory
STAT3DA/P	diplôme d'études approfondies en statistique (pratique de la statistique) (5 credits)	