# Tools for the development of pharmaceuticals and other therapeutic modalities

**Lecturers**
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**Course mnemonic**
BMOL-G4410

**ECTS credits**
5 credits

**Language(s) of instruction**
English

**Course period**
First term

**Campus**
Erasme

## Course content

1. **Pharmacology**
   - Introduction and « From bed to bench side » research situations
   - In vitro and in vivo Toxicology
   - Genotoxicity & Carcinogenicity + Teratogenicity
   - Safety Pharmacology and medical devices
2. **Clinical research**
   - Introduction
   - Historical view
   - Types of clinical research
   - Clues for the success of clinical research
   - Oncology as an example
   - Phases of clinical trials
   - Implications of investigators and patients
   - Evaluation of side effects
   - Data monitoring committees
   - Recent evolution of clinical research and next study designs
   - Questions to ask in relation to the results of clinical trials
   - Ethics and Clinical research
   - Clinical research in practice
3. **Biostatistics**
   - Using the statistical software jamovi to perform:
     - basics hypothesis tests
     - ANOVA methods
     - multiple regressions
   - critical analysis of the methodology of an article

## Objectives (and/or specific learning outcomes)

At the end of the course, the learner will be able to undertake and follow the development of a drug and to interpret preclinical experimental data. The student will also be able to conduct clinical trials and analyze their statistics using computer tools and interpret them critically. The learner will have to be able to take into account the economic, ethical and regulatory aspects involved in the development of a new diagnostic and therapeutic approach.

## Pre-requisits and co-requisits

### Pre-requisites courses

PHAR-G3302 | Pharmacologie | 5 crédits

## Teaching method and learning activities

Interactive lectures and seminars on the computer

### Contribution to the teaching profile

The aim of this course is to train student to become researchers capable of conducting and interpreting scientific projects in research and development within universities, the pharmaceutical industry as well as in education, by combining their rigorous knowledge of scientific approaches and technical mastery guided by ethical and deontological rules. The student will be able to rely on his skills in fundamental and applied research.

### Course notes

Université virtuelle

## Other information

### Place(s) of teaching

Erasme

### Contact(s)

Caroline Verhoeven (Caroline.Verhoeven@ulb.be)

## Evaluation method(s)

written examination

### Evaluation method(s) (additional information)

The student will be evaluated by an integrated closed-book exam, integrating the different aspects of this course. A scientific article in English will be made available to students during the exam. This article will be necessary to solve certain questions. This exam will include open questions as well as MCQs and/or true/false.

### Determination of the mark (including the weighting of partial marks)

The final mark of this course corresponds to the total of the points of the exam normalized to a maximum of 20. As there is one exam for the different aspects, we will NOT accept to transfer a partial result or to validate a part of this course.

### Main language(s) of evaluation

English

### Other language(s) of evaluation, if applicable

French

## Programmes

### Programmes proposing this course at the faculty of Medicine

MA-BIMED | Master in Biomedical Sciences | finalité Research/unit 1 and finalité Professional/unit 1