

Course Specifications

Valid as from the academic year 2020-2021

Epidemiology and Clinical Trials (C002884)

Due to Covid 19, the education and evaluation methods may vary from the information displayed in the schedules and course details. Any changes will be communicated on Ufora.

Course size (nominal values; actual values may depend on programme)
Credits 5.0 Study time 150 h Contact hrs 60.0 h

Course offerings and teaching methods in academic year 2020-2021

Offering	Language	Location	Teaching Method	Hours
A (semester 1)	English	Gent	lecture	20.0 h
			self-reliant study activities	5.0 h
			guided self-study	5.0 h
			seminar: coached exercises	30.0 h
			online seminar: coached exercises	0.0 h
			online lecture	0.0 h
			seminar: coached exercises	30.0 h
B (semester 1)			self-reliant study activities	5.0 h
			guided self-study	5.0 h
			lecture	20.0 h
			online lecture	0.0 h
			online seminar: coached exercises	0.0 h

Lecturers in academic year 2020-2021

Van Oyen, Herman	GE39	lecturer-in-charge
Vandebosch, An	WE02	co-lecturer

Offered in the following programmes in 2020-2021

Programme	crdts	offering
Master of Science in Teaching in Social Sciences (main subject Sociology)	5	A
Master of Science in Bioinformatics (main subject Systems Biology)	5	A
Master of Science in Sociology	5	A
Master of Science in Statistical Data Analysis	5	A, B
Exchange Programme in Political and Social Sciences	5	B

Teaching languages

English

Keywords

Epidemiological study, causality, clinical trial; confounding, randomization, risk, study design, screening

Position of the course

This course builds on the course on Principles of statistical data analysis, Analysis of continuous data and Categorical Data Analysis to teach knowledge and ideas common to drawing evidence from observational as well as randomized studies with a focus on applications in medicine and public health. It will provide the student with an understanding of the epidemiological and statistical principles, methodology and concepts involved in population and clinical research. The student should acquire the skills to design an epidemiological study or clinical trial, be aware and understand the limitations related to epidemiological studies and clinical trials, be aware of formal guidelines and be able to analyze the data according to appropriate statistical

techniques.

Contents

- Introductory concepts
 - Frequency measures of disease: prevalence and incidence rates
- ### Observational studies
- Measures of disease frequency (Incidence density, Cumulative Incidence; prevalence)
 - Standardization (direct and indirect, SMR)
 - Measures of effect (causality, risk difference, relative risk, odds ratio, attributive risk)
 - Life tables, hazard rates, hazard ratios
 - Diagnostics (sensitivity, specificity, likelihood ratios, Bayes rule, ROC curves)
 - Precision and validity (bias, confounding, elimination of confounding, matching)
 - Epidemiological study design (cross-sectional study, case-control study, cohort study, ecological study, clinical trial, community trial)
 - Causality versus association
 - Adjusting for known confounders
 - Sensitivity analysis for unknown confounders
- ### Clinical Trials
- Protocol document and the role of the statistician therein
 - Types of experimental designs (parallel, cross-over, factorial)
 - Endpoints
 - Sample Size/Power calculations
 - Treatment allocation
 - Data analysis and prognostic factors
 - Concepts and methodology for (data-dependent) stopping and early termination of trials (interim analysis, adaptive designs and data monitoring committees)
 - Meta-analysis
 - Reporting of results, potential pitfalls and data quality

Initial competences

Basic statistical concepts

Final competences

- 1 The student has knowledge of statistical methods (including designs) for the analysis of epidemiological studies and clinical trials.
- 2 The student can give well-argued advice on epidemiological study and clinical trial designs.
- 3 The student can properly perform advanced clinical trial and epidemiological data analyses.
- 4 The student can draw appropriate conclusions from statistical analyses related to the epidemiologic studies and clinical trial taking into account possible study design related bias.
- 5 The student can report the results to scientists from subject matter fields.
- 6 The student can critically comment on published epidemiological and clinical research.

Conditions for credit contract

Access to this course unit via a credit contract is determined after successful competences assessment

Conditions for exam contract

This course unit cannot be taken via an exam contract

Teaching methods

Guided self-study, lecture, self-reliant study activities, seminar: coached exercises, online lecture, online seminar: coached exercises

Extra information on the teaching methods

Student project: critical evaluation of a published or ongoing epidemiological study.

Learning materials and price

Syllabus, overheads, exercises handout Cost: 10 EUR
Epidemiology: Beyond the basics. Szklo M., Nieto J. 2nd edition. Jones and Bartlett Publ, 2007 (ISBN-13: 9780763729271/ISBN-10: 0763729272). Cost 50 EUR.

References

- Observational Studies. Rosebaum P.R., Springer Verlag, New York, 1995.
- Foundations of epidemiology. D.Lilienfeld, P. Stolley. Oxford University Press, New York, 1994.
- Modern epidemiology. K. Rothman. Little, Brown & Co, Boston, 1986
- Epidemiology kept simple: an introduction to classic and modern epidemiology. B Gerstman. Wiley-Liss, Inc, New York, 1998.

- Statistical Methods in Epidemiology. H.A. Kahn, C.T. Sempos, Oxford University Press, New York, 1989.
- Statistical Methods in Epidemiology. Clayton D., Hills M., Oxford University Press, New York, 1995.
- Fundamentals of clinical trials. Friedman L., Furberg C., DeMets D. Springer-Verlag, New York 1998 (3rd edition)
- Pharmaceutical Statistics: practical and clinical applications. Bolton S., Bon C. Informa Health Care, 2004.
- Statistical Issues in Drug Development. Senn S. Wiley, Hoboken and Chichester (1997).
- Clinical Trials: A methodologic Perspective. Piantadosi S. Wiley & Sons, New Jersey, 2005 (2nd edition).

Course content-related study coaching

Group and individually based support during practical sessions.

Evaluation methods

end-of-term evaluation and continuous assessment

Examination methods in case of periodic evaluation during the first examination period

Open book examination, oral examination

Examination methods in case of periodic evaluation during the second examination period

Open book examination, oral examination

Examination methods in case of permanent evaluation

Assignment

Possibilities of retake in case of permanent evaluation

examination during the second examination period is possible

Extra information on the examination methods

Periodical evaluation: oral examination after written preparation involving the critical evaluation of a scientific paper (open book) (epidemiology) and open written exam (clinical trials).

Non-periodical evaluation: marks for take home problem sets will be based on written reporting, and marks for the project will be based on both written and oral reporting

Calculation of the examination mark

Theory and exercises: periodical evaluation (50%) and non-periodical evaluation (2 take home problem sets (25%) and 1 project (25%)). To pass for this course, the student must pass for both the periodical and the non-periodical evaluation.

If the student fails for this course in the first examination period and if he/she wants a retake in the second examination period, the non-periodical evaluation will be presented in a revised form in the second examination period.