



UNIVERSITÀ DEGLI STUDI DI PALERMO

DEPARTMENT	Scienze Economiche, Aziendali e Statistiche		
ACADEMIC YEAR	2023/2024		
MASTER'S DEGREE (MSC)	STATISTICS AND DATA SCIENCE		
INTEGRATED COURSE	BIostatISTICS - INTEGRATED COURSE		
CODE	23163		
MODULES	Yes		
NUMBER OF MODULES	2		
SCIENTIFIC SECTOR(S)	SECS-S/05		
HEAD PROFESSOR(S)	ATTANASIO MASSIMO	Professore Ordinario	Univ. di PALERMO
OTHER PROFESSOR(S)	ATTANASIO MASSIMO	Professore Ordinario	Univ. di PALERMO
CREDITS	9		
PROPAEDEUTICAL SUBJECTS			
MUTUALIZATION			
YEAR	1		
TERM (SEMESTER)	2° semester		
ATTENDANCE	Not mandatory		
EVALUATION	Out of 30		
TEACHER OFFICE HOURS	ATTANASIO MASSIMO Wednesday 10:00 - 12:00 dseas ed 13 studio 104		

PREREQUISITES	Knowledge of inferential statistics also for linear models, basics of survival analysis, good knowledge of R software and SAS
LEARNING OUTCOMES	Knowledge and comprehension skills. The student must acquire: i) a technical language typical of biostatistics that will be useful for reading scientific articles and books and must be able to communicate appropriately with experts (doctors, biologists, etc.); ii) statistical methods dedicated to the analysis of medical data; iii) the ability to distinguish between different ways of acquiring data. Ability to apply Knowledge and Understanding. The student must be able to distinguish between i) different types of data (individual or aggregated; longitudinal or single-spell), ii) different types of surveys (prospective/retrospective, longitudinal, observational), to detect statistical methods appropriate to the type of data and the objectives. Autonomy of Judgement. The student should be able to i) comment/report on the results of medical/epidemiological studies adopting a statistical language; ii) discriminate between the pros and cons of different statistical methods and techniques in medical and clinical studies. Communication skills. The student must be able to i) write a technical report using language appropriate to the recipient, ii) present technical reports using language appropriate to the audience; iii) (de)write "the statistical method" for scientific work in the medical field. Learning ability. The student must be able to (i) do literature research among national and international statistical scientific literature in the medical field; (ii) adapt his/her knowledge to the 'needs of the client'; (iii) use his/her knowledge to solve new problems.
ASSESSMENT METHODS	The evaluation is carried out through a written test and an oral examination, subject to passing the written test. The written test will be conducted in English. The oral test will normally be conducted in English. The teacher may, if deemed appropriate, have the candidate present one or more topics in Italian. WRITTEN TEST - Advanced Survival Analysis The written test is aimed at measuring the knowledge and skills possessed by the student and his or her ability to report them in a written paper that also accounts for the statistical language skills possessed. The test lasts a maximum of three hours and consists of two open-ended practical and theoretical questions (with a maximum of three sub-questions each). Students are given an A4 sheet of paper on which to write down their notes. The texts, which are well-defined, clear, of varying difficulty and unambiguously interpretable, allow the students to formulate their answers independently and are structured so that they can be compared with the answers given by the other students. The threshold of sufficiency, propaedeutic to access to the oral test, consists of the adequate use of terms relating to the basic concepts only, and i) in the case of a practical question, with the application of the appropriate statistical methodology even if vitiated by a mere calculation error (provided that it is consistent with the methodology itself); ii) in the case of a theoretical question, in the consistency (also statistical) of the answer, even if not exhaustive of the subject. ORAL TEST - Advanced Survival Analysis The oral test aims to deepen the student's written work and learning. It will consist of at least two questions aimed at better assessing the student's knowledge, skills and transversals with the topics of the courses taken previously, as well as his or her ability to convey the information in an appropriate statistical language. The test may also consist of the performance of a practical example. The threshold of sufficiency of the oral test will be reached when the student has shown knowledge and understanding of the topics at least in general terms (definition of concepts) and has minimum applicative skills, consisting in the exemplification of simple concrete cases (typically inherent to the topics covered in the initial part of the course). The more brilliantly the candidate has passed the written test and has shown, in the oral test, his or her argumentative and expositive abilities, as well as his or her statistical language skills, the more positive the assessment will be. FINAL EVALUATION METHOD - Advanced Survival Analysis The final assessment of the examination will consider three aspects: i) the mastery of the topics; ii) the ability to define appropriate models and statistical approaches, and iii) the language proficiency evaluated in the written and oral examinations. The grade range will allow the teacher to take into account the contextual factors of the examination (such as active participation during the lectures and tutorials or the presence of some disabilities).

	The grade will be in thirtieths, resulting from the simple arithmetic mean of the marks obtained in the written and oral examination. VERIFICATION of Statistical models in clinical research Verification of learning takes place through: - For those who take the exam during the session immediately following the one in which the course is delivered: Delivery of a report assigned during the course to be carried out individually aimed at i) identifying the key elements of a study protocol (endpoints, eligibility criteria...), ii) outlining the fundamental characteristics of the study (design, randomisation, masking...), iii) identifying possible sources of bias, iv) hypothesising a new randomised and a non-randomised study and discussing advantages and disadvantages of the two approaches. The paper is due one week before the oral test. The oral test will consist of a discussion of the analysis and results described in the final report. - For those taking the exam in other sessions: Oral test on all topics covered during the course. FINAL EVALUATION METHOD - Statistical models in clinical research The final assessment of the examination will consider three aspects: i) the mastery of the topics; ii) the ability to define appropriate models and statistical approaches; and iii) the language skills assessed in the written and oral examinations. The grade range will allow the teacher to consider contextual factors of the examination (such as active participation during lectures and tutorials or the presence of some disability). The mark will be in thirtieths, resulting from the simple arithmetic mean of the marks obtained in the written and oral examination. GRADE DETERMINATION - Biostatistics The final mark for the course will be the result of the weighted arithmetic mean of the marks obtained in the two modules, weighted 0.66 for Advanced Survival Analysis and 0.34 for Statistical models in clinical research.
TEACHING METHODS	frontal lectures in English and computer lab exercises.

MODULE STATISTICAL MODELS IN CLINICAL RESEARCH <i>Prof. MASSIMO ATTANASIO</i>	
SUGGESTED BIBLIOGRAPHY	
Meinert C. Clinical Trial , Overview 37-51, voce nel volume Biostatistics in Clinical Trials, Carol K. Redmond (Editor), Theodore Colton (Editor) Wiley. Machin D, Campbell M. Walters S (2007) Medical Statistics capp 12, 13, 14, 15, Wiley Rosenberger, W. F., & Lachin, J. M. (2015). Randomization in clinical trials: theory and practice. John Wiley & Sons. cap 1-3 Materiale fornito dal docente (in inglese).	
AMBIT	50607-Statistico applicato
INDIVIDUAL STUDY (Hrs)	54
COURSE ACTIVITY (Hrs)	21
EDUCATIONAL OBJECTIVES OF THE MODULE	
The student must i) know basics of randomised and non-randomised trials, ii) be able to interpret relevant elements of the trial (sample size, study quality, statistical analysis of results), iii) apply some methods devoted to reduce bias in non-randomised studies (propensity score methods)	

SYLLABUS

Hrs	Frontal teaching
2	Basic concepts of medical research. Overview of epidemiological studies versus clinical studies
2	Clinical trials: protocol structure and guidelines for the statistical plan. Definitions, Eligibility criteria, Ethics, Endpoints,
2	Randomized clinical trials: examples and comparison of different randomisation techniques
2	Randomized Clinical Trials: Bias, Blinding and Sample size
4	Methods for bias reduction for non-randomised clinical studies (propensity score)
Hrs	Practice
4	Research of randomized clinical trials and analysis of the protocols of randomized clinical trials
2	Randomization and sample size in R
3	Examples of propensity score analysis in R

MODULE ADVANCED SURVIVAL ANALYSIS

Prof. MASSIMO ATTANASIO

SUGGESTED BIBLIOGRAPHY

Collett D. (1994), Modelling survival data in medical research (ch. 1, 2,3 e 4), Chapman & Hall.
 Klein Moeschberger (1997), Survival Analysis, ch.8 e 9 Springer
 Willett, Singer (2003), Applied Longitudinal Data analysis, Oxford University Press (ch.10 and 11)
 Putter, H., Fiocco, M. and Geskus, R. B. (2007), Tutorial in biostatistics: competing risks and multi state models. Statistics in Medicine, 26: 2389–2430 Sections 1;2,3.1,3.2,3.3;3.3.1.

AMBIT	50607-Statistico applicato
INDIVIDUAL STUDY (Hrs)	108
COURSE ACTIVITY (Hrs)	42

EDUCATIONAL OBJECTIVES OF THE MODULE

The primary objective of the course is the acquisition of statistical skills to 1) provide a statistical basis for the design of a clinical trial, 2) process and analyse medical and healthcare studies data; 1) provide a foundation of statistics for the design of a clinical trial; 2) process and analyse data from medical and health care studies.
 The student will be able to: 1. know how to process and analyse survival data according to the PH Cox scheme; 2. apply and know the advantages and disadvantages of different extensions of this model (discrete-time models; stratification; competitive risk models, models with time-dependent variables).

SYLLABUS

Hrs	Frontal teaching
2	Introduction, objectives and general information on examination methods
4	Survival data: the discrete case and the continuous case. Survival function, hazard function and cumulative hazard, life expectancy
4	Kaplan Meier, Nelson Aalen and actuarial estimators. Point and interval hazards. The log rank test. Semi-parametric methods: graphical methods and proportionality tests, Cox model, how to construct the partial likelihood function, how to choose a model, significance of estimated parameters, baseline and survival function.
14	Extensions of the Cox model: discrete-time models; stratification; time-dependent variables; time-dependent effect variables; multi-state models; competitive risk models.
Hrs	Practice
4	Cox's model, and R and SAS software
14	Cox model extensions, Software: R and SAS