

Basic Methodology in Clinical Research

Code: 42148
ECTS Credits: 10

Degree	Type	Year	Semester
4312326 Applied Clinical Research in Health Sciences	OB	0	1

The proposed teaching and assessment methodology that appear in the guide may be subject to changes as a result of the restrictions to face-to-face class attendance imposed by the health authorities.

Contact

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Use of Languages

Principal working language: spanish (spa)

Teachers

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Ignacio José Gich Saladich
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External teachers

David Rigau Comas
Hector Pardo Hernández
Judit Solà Roca
Marta Roqué Fíguls

Prerequisites

Requirements for admission to the master's degree and knowledge of technical english at the reading level

Objectives and Contextualisation

The objective of this module is to understand the methodological foundations of clinical research epidemiological reasoning to be able to design and carry out specific studies on practical problems clinical and community. In this module the student will be trained to know the types of clinical research, the main medical databases and to be able to do critical reading of articles and systematic reviews. This way the student will know the different designs of studies, the main epidemiological measures, the parameters to determine its validity and the most relevant statistical analysis for each design. Knowledge of the current legislative aspects for the conduct of the investigation and the ethical principles they will also be an outstanding aspect to be developed in this module.

Definitely, the realization of this first module must be used so that the student is able to make judgments critics and to begin research in health sciences familiarizing with the scientific, most important methodological, ethical and legislative

Competences

- Act respecting the Independent Ethics and legal aspects of the research and of the professional activities.
- Communicate and apply knowledge to the public and cultural debate.
- Critically evaluate, identify and classify the sources of scientific information according to the type of evidence and the scientific relevance.
- Development of habilidades autoaprendizaje y su formación Motivación to continue to postgraduate level.
- Development scientific knowledge, creativity and Critical Thinking.
- Differentiate lending and the methodology applied scientific research.
- Identify and comprehend the continuous advance and looking retos
- Participate in the development of a protocol for basic, clinical or experimental research, based on scientific methodology.
- Prove that the methodologies covering estadísticas básicas utilizadas in the biomedical and clinical estudios y análisis use the tools of the modern computational technology.
- Recognize and explain the ethical, regulatory and financial context in which biomedical research must be conducted
- Working as part of a group along with other professionals, understand their views and cooperate constructively.

Learning Outcomes

1. Act respecting the ethical and legal aspects of research and professional activities.
2. Apply the general principles of Bioethics and Health Economics in scientific activity.
3. Apply the general principles of statistics.
4. Classify the type of evidence.
5. Communicate and apply knowledge to the public and cultural debate.
6. Describe the characteristics and compare the different methods used in the selection, design and information gathering in research.
7. Describe the characteristics and implications of the stages of R + D + I in Health Sciences.
8. Detail the means of dissemination of scientific activity.
9. Develop scientific knowledge, critical thinking and creativity.
10. Develop self-learning skills and motivation to continue their education at the graduate level.
11. Identify and understand the ongoing progress and challenges in search
12. Identify sources of scientific information.
13. Raise the possible causal relationships.
14. Recognize the different types of research.
15. Set objectives, assumptions, operational definitions and integrate it into a theoretical framework.
16. Working as part of a group along with other professionals, understand their views and cooperate constructively.

Content

a) Types and stages

Paradigms in research: quantitative research and qualitative research. Terminological diversity in the type of research. Overview of the research process. Objectives. Hypothesis. Operational definitions. Integration in a theoretical framework. Preclinical development. Clinical development: phases. Post-authorization. Biomarkers and subrogated variables. Models: screening tests, bioassays, simulations. Validity (predictive, apparent, construct). Efficacy, effectiveness, efficiency, effectiveness.

b) Conceptual phase:

Sources of scientific information: MEDLINE, EMBASE, other databases. Metacercators. Criteria and tools for efficient information research. General criteria for critical reading depending on the type of design. Quality of evidence. Degrees of recommendation.

c) Methodological elements:

General characteristics of the different designs: strengths and weaknesses of each one: studies of cohorts, cases and controls, prevalence, experimental. Systematic reviews. Frequency and association measures. Internal and external validity. Description of the population and sample concepts. Explanation of the techniques of sampling. Information necessary for the calculation of the sample size. Methods for collecting information. Quality of measurement. Selection and definition of variables. Measurement scales. Types of questionnaires. Sources of information to obtain data. Types of questions. Writing and order of questions. Questionnaire format. Validation: Validity, Reliability.

d) Analysis, interpretation and dissemination

General statistical principles. Introduction to statistics. Description of the types of existing variables, as well as the most suitable statistics for each one of them. Introduction to the contrast of hypotheses. Causal criteria: individual assessment of its relevance. Scientific publications and dissemination. Checklists by authors, reviewers and editors of medical journals. Bibliometry.

e) Ethics, legislation and financing

Protection of the rights of patients and animals. International ethical codes. Ethical committees. Quality Culture: Good Practices. Autonomic, national and supranational legislation. Guidelines for biomedical research of Regulatory Agencies. The evolution of the national regulations: the new Law on Biomedical Research. Sources and types of financing. National programs. Research projects. ANEP. Patents. Conflict of interests.

See program 2021-22 Virtual Campus:

<https://cv.uab.cat/protected/index.jsp;jsessionid=DDB751906148A026C75F6765E43B1676>

Methodology

GUIDED SESSIONS: The theoretical classes will be face-to-face to explain the main concepts of the course. However, the core of the program will be based on the strategy of the learning based on problems, for that reason will require of the students a previous work of reading and critical analysis of the aspects to analyze. The classes will be supported by audiovisual media, and the student will be encouraged to deepen into the knowledge acquired in the classroom through the use of the bibliography and other elements. There will be sessions of debate on specific topics.

SEMINARS: Given the character and orientation of the subject, the seminars will play a key role in the learning of the subject, which is why the stimulation of the participation and its previous preparation is very important to ensure maximum performance in the acquisition of objectives of each one of the seminars. The student will have to carry out an electronic Evidence Based Medicine (MBE) electronic course.

SELF-LEARNING ACTIVITIES: Problem-based learning requires an important involvement of the student in the preparation of theory classes and supervised practices. A system will be assigned to have the materials,

bibliography and other necessary tools to be able to develop this phase in an autonomous way, which will imply that the students must participate very actively in the classes and seminars both face-to-face or virtual.

Annotation: Within the schedule set by the centre or degree programme, 15 minutes of one class will be reserved for students to evaluate their lecturers and their courses or modules through questionnaires.

Activities

Title	Hours	ECTS	Learning Outcomes
Type: Directed			
Classroom practices: Approach and resolution of practical cases	17	0.68	3, 4, 6, 8, 12, 13, 15, 16
Concept classes with support from ICT and group discussions	30	1.2	2, 3, 4, 7, 6, 9, 8, 11, 12, 13, 15, 14
Laboratory Practices (LABP)	3	0.12	3, 4, 6, 8, 12, 13, 15, 16
Seminars for discussion of texts	12.5	0.5	1, 3, 4, 6, 10, 8, 12, 13, 15, 16
Type: Supervised			
Tutoring. Supervision and support in carrying out work	82.5	3.3	3, 4, 6, 9, 8, 12, 13, 15
Type: Autonomous			
Public presentation of works. Individual presentations and round of valuations	20	0.8	3, 4, 6, 9, 10, 8, 12, 13, 15, 16
Study	60	2.4	3, 4, 6, 10, 8, 12, 13, 15
Writing of works and elaboration of monographic topics	20	0.8	3, 4, 5, 6, 9, 8, 12, 13, 15

Assessment

System of evaluation of the acquisition of the competencies and system of qualifications

The competences of this module will be evaluated through: exams, individual and group work and public presentations.

The evaluation system is organized in 3 sections, each of which will be assigned a specific weight in the final grade:

- Written evaluative tests of the acquisition of the information contents, with an approximate global weight between 30 and 40%
- Discussions and presentations in the classroom, with an approximate global weight of between 30 and 40%
- Delivery of works, evaluating one or more jobs, with a global weight between 30 and 40%

Minimum compliance will be established from which the student will be in a position to pass the module.

Assessment Activities

Title	Weighting	Hours	ECTS	Learning Outcomes
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Delivery of work	30%	1	0.04	3, 4, 6, 9, 8, 11, 12, 13, 15
Discussions and presentation in the classroom	35%	2	0.08	3, 4, 5, 6, 9, 10, 8, 12, 13, 15, 16
Written test	35%	2	0.08	1, 2, 3, 4, 7, 6, 9, 8, 11, 12, 13, 15, 14

Bibliography

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Software

Microsoft Teams