UNIVERSITÀ
DEGLI STUDI DI MILANO-BICOCCA

COURSE SYLLABUS

Pharmacoepidemiology

2526-1-F8205B020

Learning objectives

The aim of the course is to analyse the main models for clinical and/or farmacoepidemiology studies, allowing the students to draft the final report of an experimental-clinical or observational study.

Contents

- Clinical trials and observational studies
- Healthcare utilization databases
- Features related to study design
- Sources of bias
- Insights: farmacovigilance, Drug utilization research and Pharmacovigilance, detection bias, Misclassification bias, and Measured and unmeasured confounder

Detailed program

1. Introduction

- Epidemiological approach
- Inadequacy of clinical trials
- Inadequacy of adverse drug reaction reports database
- Inadequacy of pharmacovigilance monitoring system
- Pharmacoepidemiology
- Drug utilization research
- Healthcare utilization databases

2. Pharmacy utilization and determinants of drug utilization

3. Pharmacovigilance

4. Detection bias

5. Exposure misclassification

6. Time related bias:

- Immortal time bias
- Immeasurable time bias
- Time-window bias

7. How to control confounding effects by statistical analysis

- Stratification
- Multivariate models
- Propensity score

8. Methods to control for unmeasured confounding in pharmacoepidemiology

- Rule-out approach
- Monte-Carlo sensitivity analysis
- Propensity score calibration

9. Case-only designs

- case-crossover
- case time control
- Self-controlled case-series

Prerequisites

No prerequisite

Teaching methods

The course includes front lectures and some hours in the laboratory to perform the work-group required for the final exam (for those attending).

Only During the **Covid-19 emergency period**, the lectures will be carried out through telematic mode (streaming and videotaped lectures). The videotaped lectures will be uploaded to the course page through the e-learning platform.

Assessment methods

Students attended:
The exam consists of two parts: (a) Group work, involving the development of a research protocol for an observational study. The written protocol must be submitted to the techer by the specified deadline. (b) Final oral examination, which includes open-ended questions aimed at assessing the students' understanding of the course topics. The discussion will begin with the research protocol presented in the first part.

Students not attended:
The exam consists of an oral exam during which the students will be invited to discuss with the teacher to the main topics covered during the course, with the intent of verifying the global learning of the course.

Textbooks and Reading Materials

The necessary study material will be uploaded in the e-learning platform.
Reference text:
Giovanni Corrao. Real world evidence. Buone pratiche della ricerca basata sull'osservazione del mondo reale. 2019, Il Pensiero Scientifico

Semester

II semester, IV cycle

Teaching language

Italian

Sustainable Development Goals

GOOD HEALTH AND WELL-BEING