UNIVERSITY OF COPENHAGEN
DEPARTMENT OF DRUG DESIGN AND PHARMACOLOGY

Pharmacovigilance Research Centre

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse reactions and other medicine-related problems. Pharmacovigilance is closely related to pharmacoepidemiology, the science that applies epidemiologic methods to study the use, effectiveness, safety, and value of pharmaceuticals.

Our research methods are:

- Proactive surveillance and signal detection using big healthcare data
- Design of rapid risk evaluation systems
- Multi-database network studies of rare adverse events

Pharmacovigilance is of major importance to Danish society. As part of the optimized treatment of patients with pharmaceutical interventions, it is important to be aware of potential adverse drug reactions, how these can be detected and treated, and ultimately how they potentially can be avoided.

The Pharmacovigilance Research Centre is a Novo Nordisk Foundation-funded initiative headed by Professor Morten Andersen. We aim to develop new methods and tools and generate new evidence that will shape future drug safety surveillance. Prospectively, our research will contribute to the evaluation of benefits/risks of therapy, and enable patients, healthcare professionals, regulators, and the pharmaceutical industry to improve drug use and prevent drug-related problems for the benefit of public health. We aspire to strengthen the field of pharmacovigilance as an academic discipline and create a truly interdisciplinary research field exploiting adjacent disciplines like pharmacy, regulatory science, and pharmacometrics, and benefiting from the tremendous resource of the Danish National Registers.

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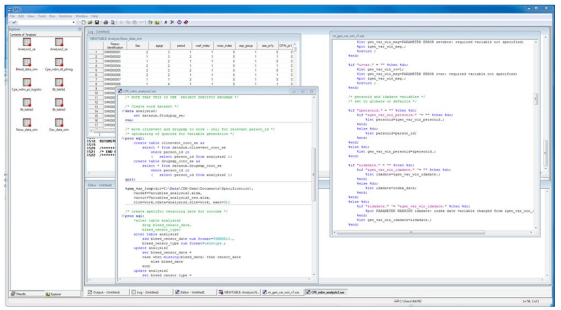
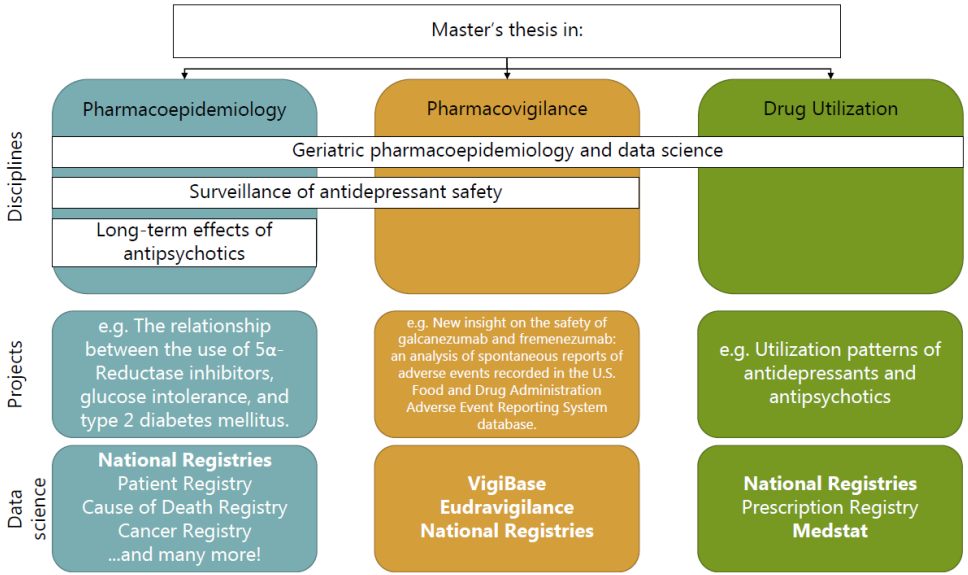
Master's thesis at the Pharmacovigilance Research Centre



Being a Master's thesis student in the PVRC

As a Master's thesis student at the Pharmacovigilance Research Centre (PVRC) you will be introduced to the field of pharmacoepidemiology, learn how to program in statistical software (SAS, Stata, or R), and become familiar with the opportunities of *big healthcare data* such as our unique Danish Registries. We share our Pharmacoepi Computer Lab with the Pharmacometrics Group. Here you can perform your analyses and share knowledge with other students.

We strongly encourage you to select our elective course Pharmacoepidemiology and Pharmacovigilance (block 3, C) and an individual study unit, which will provide you with basic knowledge of pharmacoepidemiological methods and introduce you to the statistical software that you will use during your thesis. Other relevant courses could be Regulatory Science (block 4, C) and Design and Analysis of Experiments (block 3, B).



Geriatric pharmacoepidemiology

Older adults are the main consumers of drugs but are rarely included in pivotal randomized clinical trials. Hence, pharmacoepidemiology is central to understanding drug safety and effectiveness in these patients. The aim is to develop methods, applications, and dissemination of geriatric pharmacoepidemiology. Also, we aim to implement applied data science techniques for subgroup identification of older patients that may benefit more or be more at risk with pharmacological therapies.

Projects

- Comparison of misclassification of exposure among four methods used for computing the duration of pharmacological treatment episodes in secondary data sources
- The relationship between the use of 5α-Reductase inhibitors, glucose intolerance, and type 2 diabetes mellitus.
- New insight on the safety of galcanezumab and fremenezumab: an analysis of spontaneous reports of adverse events recorded in the U.S. Food and Drug Administration Adverse Event Reporting System database.

Psychiatric pharmacoepidemiology

The use of antidepressants and antipsychotics has increased significantly in the last decades and Denmark is among those countries with the highest consumption. However, both drug classes are known to be associated with adverse drug reactions. In psychiatric pharmacoepidemiology, we wish to improve the detection of these potential associations and quantify the risks of both short and long-term effects. Professor Morten Andersen heads the research in collaboration with the two Ph.D. students Mia Aakjær and Reeha Sharon.

Projects

- Risk of bleedings associated with combined treatment with selective serotonin-reuptake inhibitors and oral anticoagulants
- Cardiac-risk associated with long-acting antipsychotics in Schizophrenic patients.