

PHARMO Newsletter November 2011

The PHARMO Institute for Drug Outcomes Research specialises in the collection and analysis of complex, longitudinal patient-centric data, detailing the relationship between drug exposure, outcomes and costs in real-life settings.

We invite you to read our newsletter.



Database Research Opportunities

PHARMO International Research Program

Many studies and in particular post-approval safety studies are executed in multiple countries in Europe. With the aim to assist clients in co-ordinating and executing multi-database studies in Europe, the PHARMO Institute has set up an International Research Program. As with our other projects, PHARMO pan-European studies are tailor-made and may vary in scope from simple feasibility assessments for future studies to full-scale safety studies including communication with the authorities. By participating in industry-funded as well as publicly-funded multi-database studies, PHARMO has built up a network with peer databases in Europe. We aim to work efficiently with the different source populations, database structures and privacy/governance models across Europe.

Possibilities

Examples of studies co-ordinated by PHARMO include assessment of European incidence/prevalence, patterns of disease and related healthcare utilization, safety monitoring (EMA) and market uptake/drug utilization studies.

PHARMO Research

Dupuytren's contracture

A recent PHARMO study entitled: "*Dupuytren's contracture: a retrospective database analysis to determine hospitalizations in the Netherlands*" is published in BMC Research Notes. This study is a first exploration of Dupuytren's contracture in the Netherlands based on hospitalizations. We determined that each year about 40 patients per 100,000 inhabitants were hospitalized for Dupuytren's contracture. The highest prevalence (250 per 100,000) was observed among males 60-79 years of age. A total of 3,040 patients with a hospitalization for Dupuytren's contracture between 2004 and 2007 were included in the study cohort. Of these patients, 76% were male and the mean (\pm SD) age was 62 (\pm 12) years. During a median (IQR) follow-up of 2.9 (1.8-4.0) years, 523 patients were rehospitalized for Dupuytren's contracture. The median (IQR) time to first rehospitalization was 0.8 (0.4-1.9) years.

Reference: BMC Res Notes 2011, 4: 402.

PHARMO news

SAFEGUARD project: diabetes drugs

In October 2011 the SAFEGUARD - Safety Evaluation of Adverse Reactions in Diabetes - project was kicked off. New safety issues of drugs used in diabetes are constantly arising, such as potential associations with pancreatitis, pancreas cancer, bladder cancer and acute renal failure. In 2010 a widely marketed drug for the treatment of type 2 diabetes (T2DM), rosiglitazone, was taken from the market as it was associated with an increased risk of myocardial infarction, a T2DM complication it was actually supposed to prevent.

Multidisciplinary consortium

A multidisciplinary consortium of 14 centers in Europe, among which PHARMO, aims to quantify the cardiovascular, cerebrovascular and pancreatic safety risk of the T2DM drugs, in particular the more novel drugs, by investigating:

1. published clinical trials and observational studies
2. spontaneously reported adverse event reports in national and international pharmacovigilance databases
3. data from population-based health care databases capturing longitudinal drug exposure and event data on more than 1.7 million T2DM patients across Europe

To put the epidemiological results into perspective, intensive monitoring mechanistic studies in human will be conducted to further understand how and why these T2DM drugs may affect the cardiovascular, digestive or renal system. The SAFEGUARD consortium will yield a harmonized epidemiological data platform on a large T2DM population, which could easily be used to address newly occurring safety issues in the future.

SAFEGUARD is funded by the European Commission in the 7th Framework Programme.

Publications

We would like to draw your attention to recently published studies using PHARMO data and/or publications by PHARMO staff:

Cardiovascular diseases/diabetes:

- Genetic variability within the cholesterol lowering pathway and the effectiveness of statins in reducing the risk of MI. Peters BJ, Pett H, Klungel OH et al., *Atherosclerosis*, 2011, 217(2): 458-64.
- Venous thromboembolism prophylaxis after total knee or hip replacement: treatment pattern and outcomes. Penning-van Beest FJ, Overbeek JA, Meijer WM et al., *Pharmacoepidemiol Drug Saf*, 2011, 20(9): 972-8.
- Risk of cancer in patients on insulin glargine and other insulin analogues in comparison with those on human insulin: results from a large population-based follow-up study. Ruiter R, Visser LE, van Herk-Sukel MP et al., *Diabetologia*, 2011, in press.
- Dopamine agonists and ischemic complications in Parkinson's disease: a nested case-control study. Arbouw ME, Movig KL, Guchelaar HF et al., *Eur J Clin Pharmacol*, 2011, in press.

Oncology:

- Record linkage for pharmacoepidemiological studies in cancer patients. Herk-Sukel MP, Lemmens VE, Poll-Franse LV et al., *Pharmacoepidemiol Drug Saf*, 2011, in press.
- Costs of hospital events in patients with metastatic colorectal cancer. Overbeek JA, Zhao Z, van Herk-Sukel MP et al., *J Med Econ*, 2011, 14(5): 656-61.
- Use and costs of oral anticancer agents in the Netherlands in the period 2000-2008. Timmers L, Beckeringh JJ, Herk-Sukel MP et al., *Pharmacoepidemiol Drug Saf*, 2011, in press.

Other:

- Dupuytren's contracture: a retrospective database analysis to determine hospitalizations in the Netherlands. Overbeek JA, Penning-van Beest FJ, Heintjes EM et al., *BMC Res Notes*, 2011, 4: 402.
- EU-ADR healthcare database network vs. spontaneous reporting system database: preliminary comparison of signal detection. Trifirò G, Patadia V, Schuemie MJ et al., *Stud Health Technol Inform*, 2011, 166: 25-30.

Congresses

PHARMO will attend the ISPOR 14th annual European congress, November 5-8, 2011, Madrid, Spain, where we will present our latest research:

- Recent in-hospital mortality trends among patients with heart failure in the Netherlands (PCV29)
- Heart failure (re)admissions in the Netherlands: rates, length of stay and costs (PCV30)
- Population attributable risk (PAR) of macrovascular events associated with Hb1Ac, blood pressure or weight in patients with type-2 diabetes mellitus: Evidence from a Dutch cohort (PCV32)
- Comorbid cardiovascular diseases in patients with metastatic colorectal cancer (PCN10)

PHARMO workshops at ISPOR:

Workshop afternoon course on Saturday, November 5, 2011

- *Applications in using large European databases*

Workshop Session III: on Monday, November 7, 2011

- *Linking existing databases - Poisoned chalice or holy grail?*

We would like to invite you to visit our **booth #96** at the ISPOR.