Title

Signal detection and substantiation in view of the new Pharmacovigilance legislation

PhD

Pacurariu, Alexandra

Start of research 2013

Status Ongoing

Background

The new legislation reinforces the public health principle of monitoring medicinal products' benefit-risk profile throughout the product lifecycle. Part of this surveillance is acquired through the process of signal detection—namely, searching for new adverse drug reactions associated with a drug using different sources of information: spontaneous reports, literature, findings from studies. It follows from the new legislation that national competent authorities in collaboration with EMA shall monitor the data in the EudraVigilance system (European database maintained by EMA) in order to determine whether there are new risks or whether risks have changed and impact on the benefit-risk balance.

Objective

The objective of the project is to find more efficient ways of screening the spontaneous databases in context of limited resources and to explore the added value of other sources of information, with a focus on electronic health records databases. Furthermore, a coherent and rational signal management system should be built, which should allow the regulators to comply with the legislative requirements while using the scarce resources as efficiently as possible.

Regulatory impact

This knowledge will contribute to the construction of a solid system of early detection of adverse drug reactions and therefore towards a better safeguarding of public health.

Academic collaboration

Erasmus University Medical Center Rotterdam

Research track

Consumer use & safety

Research group

Coloma, Preciosa M
Straus, Sabine MJM
Sturkenboom, Miriam CJM
Keywords
signal detection, signal management, pharmacovigilance, safety

Achievement