

STELLINGEN

behorende bij het proefschrift:

Use of Real-World Data in Pharmacovigilance Signal Detection

1. Spontaneous reporting systems data are affected by both underreporting and overreporting of adverse events. (this thesis)
2. Electronic health records data have a significant potential for detecting signals for events occurring at a higher frequency in general population and those that are commonly not considered as potentially a drug-induced events. (this thesis)
3. Conducting signal detection using data from both electronic health records and spontaneous reporting system would strengthen the current way of doing signal management activities. (this thesis)
4. The collection of adverse events in spontaneous reporting system data are influenced by media reports and legal actions. (this thesis)
5. Harmonization of codes is crucial when conducting comparisons across various data sources such as spontaneous reporting system data and electronic health records data. (this thesis)
6. There is an increasing trend in pharmacovigilance to use artificial intelligence to augment decision making (Danysz, K., Cicirello, S., Mingle, E. et al. Artificial Intelligence and the Future of the Drug Safety Professional. *Drug Saf* 42, 491–497 (2019)).
7. There are no safe drugs, only safe ways of using them. (Voltaire)
8. The surveillance of drugs post-licensure has become both a science and a crusade. (Coloma P, mining electronic healthcare record databases to augment drug safety surveillance, PhD thesis, May 2012, ISBN: 978-94-6191-258-9).
9. The safest drug that no one can afford or that arrives too late is of no benefit to a patient. (Eichler HG, Baird LG, Bloechl-Daum B, et al. From adaptive licensing to adaptive pathways: delivering a flexible life-span approach. *Clin Pharmacol Ther* 2015;97:234-46.)
10. Signals can arise from a wide variety of data sources. Signal detection should follow a methodology that considers the nature of data and the characteristics of the product. (European Medicines Agency, Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management (Rev 1), 2017)
11. “A well-educated mind will always have more questions than answers.” (Helen Keller)

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