The evolution of pharmacovigilance ecosystems: does Moore's law invite the use of Ockam's razor?

Marion Mueller[1], David Lewis[1], and Amalia Alexe[2]

[1]Novartis Pharma AG
[2]Advanced Accelerator Applications SA

June 8, 2022

Abstract

"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medication-related problem", according to the WHO. With the increasing volume of legislation, pharmacovigilance systems have shifted from reactive (responding to emerging risks), to planned, active, risk-proportionate approaches operating throughout the lifecycle of medicines. Whilst medicines are beneficial to society, adverse reactions represent a significant cause of concern. They are a major cause of failed regulatory authorizations, and withdrawal from the marketplace post-approval. Evaluation of real-world data plays an increasingly important role in pharmacovigilance. There is great interest on the part of the regulators, MAHs, academia and patients in optimizing the use of safety data. Innovative approaches, including pharmacogenetics and passive measures (sensors), will lead to increased complexity in data collation and evaluation, and inevitably to an increase in the volume of case reports. There is a multiplicity of regulations and guidelines on how to manage these data, with an inherent lack of harmonization. We summarize the current characterization of safety data types, sources, and the classification of these data. Using this benchmark, we discuss the future requirements of an effective pharmacovigilance ecosystem, keeping the principle of parsimony in mind.

Hosted file

220606 Manuscript_Evolution of pharmacovigilance ecosystems.docx available at https://authorea.com/users/487872/articles/572226-the-evolution-of-pharmacovigilance-ecosystems-does-moore-s-law-invite-the-use-of-ockam-s-razor