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Commentary

Future of Pharmacovigilance and Pharmaceutical Industry

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DESCRIPTION

The field of pharmacovigilance has developed significantly in recent years. Regulators have long favored technologies such as artificial intelligence and machine learning to monitor patient safety, a trend that has accelerated during the pandemic.

Today, the development of mobile applications, digital health devices, and social media are setting new standards in patient engagement. Recent statistics highlight the tremendous value of social media monitoring and provide valuable drug-related information. In addition to this proactive monitoring, it provides early warning of new adverse events supports drug development and helps avoid avoidable litigation.

Social media, clinical data and electronic patient records; claims files; regulatory reports and filings from various disciplines. Secondary data referencing poses unprecedented difficulties in retrieving and combining "traditional" datasets. Considering that the use of secondary data by medicinal products is not mandatory from a regulatory point of view, it is still in its early stages at this time. Recently, technology providers have begun offering robust and flexible platforms to help life sciences organizations process and combine multiple file types and integrate social media streams into their pharmacovigilance methods. Advanced algorithms and imbalance checks have been developed to enable traditional automated reporting and social media streams.

Secondary data referencing and advanced signal detection technology help detect security risks faster and reduce risk. The covid-19 pandemic has caused a surge in innovation across the life sciences industry. This included the development, approval, manufacturing and delivery of vaccines and therapeutics in just a few months and on an unprecedented scale. The pandemic has also led to a surge in pharmacovigilance innovation. New initiatives to review and evaluate large and diverse data sets, including accelerating the development of pharmacovigilance techniques, streamlining adverse event collection, assessment, and reporting, and broader acceptance of the use of real-world data.

Additionally, the covid-19 pandemic has increased awareness of the need to report drug-related adverse reactions, changing the trend of reporting directly to national authorities rather than manufacturers, and increasing the profile of pharmacovigilance in general. For example, in Europe in 2021, the number of reports (781,632) submitted directly by patients and consumers through National Copetent Authorities (NCAs) and marketing authorization holders will increase four-fold (+443%) year-on-year, mainly due to COVID-19. This trend is likely due to increased awareness of AE reporting due to the pandemic and is facilitated by new technologies (electronic forms and apps) that streamline the collection of AEs directly from reporters. It will be interesting to see how this trend continues and whether reporters tend to file more AEs directly with authorities rather than manufacturers.

Effective pharmacovigilance includes a multitude of end-to-end security monitoring activities across the SRM continuum, from case-to-case management to aggregated reporting, signal detection, risk benefit assessment, and risk mitigation. Thousands of Adverse Event (AE) cases are typically processed manually by a global case work team involved in data entry, quality control, and medical review of safety case reports in the safety database. Some of these are promptly reported to regulators by filing teams. In addition, our regular aggregate reporting to regulatory authorities worldwide includes a review of cumulative safety information from various sources. Subject matter experts also focus on complex security areas such as signaling, benefit-risk assessment, and security issue mitigation activities.

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