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The Increasing New Hurdles in Pharmacovigilance in this Era of Covid-19

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Introduction

In the midst of a global health crisis, the need of monitoring the safety of medications, vaccines, and medical devices has been emphasised. While the healthcare businesses in every country labour feverishly to develop effective vaccines, Pharmacovigilance/Drug Safety stakeholders have been diligent in monitoring their safety. However, due to operational delays caused by the pandemic, the Pharmacovigilance business has been encountering ongoing hurdles in its operations. The turbulence of the situation necessitates clinical solutions, and as a result, pharmaceutical behemoths have been pressed into action, rushing to develop time-sensitive and effective Covid-19 medications and vaccines.

The Pharmacovigilance industry takes on the duty of monitoring unknown short and long-term adverse drug responses (ADRs), which are critical in analyzing the effects of drug and vaccine use, as part of the process of finding a remedy under time limitations. As a result, developing a strong safety strategy and a long-term Pharmacovigilance system is a top priority in order to meet the challenges.

Pharmacovigilance Challenges during Covid-19

To stop the virus from spreading, countries all around the world ordered entire or partial lockdowns, resulting in the closure of Pharmacovigilance institutions. This resulted in a shift in routine audits and safety inspections, affecting the quantity of work involving non-Covid items as well. As a result of fewer trips to hospitals and a bare minimum concentration on other illnesses, the flood of information and data on non-Covid goods has steadily decreased.

Another significant problem in guaranteeing operational regularity and efficiency is the shrinking pool of professionals due to social distancing and quarantine regulations. Due to a lack of access to ADR monitoring centres and a shortage of human resources in Pharmacovigilance, reporting and collecting data at the same time has become a time-consuming task.

As the obstacles of a raging pandemic emerge, opportunities must be grabbed and solutions capitalised on in order to reduce adversity. Despite the pandemic's hardship, the Pharmacovigilance system has been integrated with healthcare staff to make it more patient-centric [1].

Pharmacovigilance Opportunities and Solutions during the Pandemic

Moving forward in the pharmacovigilance sector, industry stakeholders are progressively working toward cross-national harmonization. Now that healthcare professionals are leaving no stone unturned in their efforts to reduce the Covid-19 burden, remote reporting and data gathering has been designed for increased efficiency and patient accessibility. Pharmacists are using the internet as a tool to acquire adverse effects data from afar. Patients' active participation in safety reporting on social media and company websites has signaled the seizing of a once-in-a-lifetime opportunity [2].

With corporate communication confined to virtual conferences, the issue at hand must be to establish a solid channel for sourcing data, analytical information, and reliable safety data sharing agreements. The channel must also operate on a compatible timetable and adhere to the rules that govern it. To ensure a timely response to regulator safety inquiries, the necessary resources for the response must be identified, and the appropriate methods must be developed. Furthermore, the creation of cost-effective, paperless solutions for maintaining legacy safety data and Individual Case Safety Reports (ICSRs) is critical for industry-wide communication.

Following the identification of possible hazards, the next major duty is to design effective risk management plans. To assure prioritized public health, a robust method for developing pharmacovigilance literature screening and new writing solutions for various aggregate reports such as DSUR or complex PSURs and/or PADER (as part of patient drug safety services) must be built. Additionally, pharmacovigilance professionals must work toward the creation of world-class pharmacovigilance expert services for benefit-risk analysis and advise on strategy and new safety problems for the benefit of humanity. Finally, pharmacovigilance consulting services for system creation, audit inspections and interpretations, SOPs, and other needs must be prioritized customer safety [3].

Various Pharmacovigilance service providers have been improvising the best cost-effective end-to-end patient drug safety services to combat the aforementioned difficulties (mainly affecting North America and India). The industry will also benefit from the mitigation of these issues through the tenable creation of a Pharmacovigilance infrastructure in the upcoming operational activities [4].

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