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Rethinking pharmacovigilance efficiencies amidst APAC's diverse regulatory landscape and rising drug development costs

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Globally, the pursuit for treatments with better patient outcomes and more effective care is a never-ending quest. As diseases and viruses evolve, the research and development of new medicines and treatments has also grown rapidly. Around the world, the global funding of Emerging Biopharmaceutical companies (EBPs) has grown rapidly, from $18 billion in 2010 to over $130 billion in 2020, with a compound annual growth rate of over 20%. The growth has been so rapid in the region that, in 2020, EBPs account for around 75% of the total clinical trial volume in the Asia Pacific region.

As EBPs continue to grow their business and focus on new medicines and treatments, collaboration with Clinical Research Organizations (CROs) have become a common practice, resulting in more complex governance processes to ensure that all actions are compliant. In view of such growth trajectories, it is inevitable for EBPs to strengthen their practices in pharmacovigilance, which monitors the safety of medicines in clinical use, and during clinical trials, to minimize risks associated with drug use and maximize benefits. With a diverse cultural, language and regulatory landscape, pharmacovigilance in the Asia Pacific region has always been deemed as one of the more challenging priorities that EBPs need to navigate.

Maximising efficiencies with a centralised pharmacovigilance strategy

Traditional pharmacovigilance processes are conducted based on the regulatory requirements of individual countries, resulting in the need to set up new offices and hire relevant pharmacovigilance experts to achieve market expansion plans, which incur inevitable long-term operational costs. This is especially true in the Asia Pacific region, where languages and regulatory guidelines could be vastly different, and local pharmacovigilance expertise is essential to ensure smooth processes.

As global inflation continues to surge and regulations evolve, to achieve cost efficiencies and ensure that the relevant expertise is in place, third-party end-to-end pharmacovigilance service providers have been gaining popularity among multinational pharmaceutical corporations, as well as smaller regional pharmaceutical companies and EBPs. These service providers are often engaged to maximise efficiency in the pharmacovigilance process across multiple target markets.

For instance, IQVIA, one of the largest pharmacovigilance service providers in the field, has a dedicated team of pharmacovigilance experts based in India and China who are not only well-versed in pharmacovigilance requirements and trends in the region, but also proficient in various languages including Chinese and Japanese. Complemented by the adoption of automated bots, translation platforms and services ranging from customised service platform setup to ongoing operational management, maintenance could be conducted at high efficiency, offering 24-hour daily customer support services through a multi-hub model. This suite of pharmacovigilance service offerings does not only help to address the changing needs of pharmacovigilance in the region, but also sets new industry standards around efficiency, cost-saving, and business continuity. In many cases, these “immediate” benefits can bring greater value, as the setting up of new offices takes time.

Highly streamlined servicing structure to address diverse pharmacovigilance needs

While engaging third-party service providers to support offshore business has been a norm for various industries, the concept is still widely discussed in the healthcare and pharmaceutical sectors. A key reason for the slow uptake is the complexity of pharmacovigilance processes and requirements across different countries or regions. Instead of engaging multiple service providers across multiple markets in Asia Pacific, EBPs have been looking for ways to streamline vendor management and communication to ensure compliance and reduce effort spent on multiple vendor management. By appointing a single service provider to deliver pharmacovigilance services across multiple service hubs, they could achieve efficiency, reduce cost, attain global collaboration and automation in one go.

For instance, after a global pharmaceutical company engaged IQVIA to be their service provider in Japan, they were able to achieve a compliance and quality performance score above 99% in Jan-Dec 2021, achieving robust results above target for more than 50 consecutive months. By establishing trust through high quality services and compliance, it enables them to provide cost-optimized solutions through the transfer of data entry and quality control to other cost-optimized hubs, like data entry processing in India and quality review in China. The high retention rate of less than 8% attrition within IQVIA also helped ensure communication efficiencies, ensuring peace of mind on project efficiency.

Rising trend to engage a third-party pharmacovigilance service provider in the region

Whilst ensuring that the most effective care is provided based on the best available evidence, it is equally essential to assess the necessary resources required to maximise efficiency and minimise hiccups during the process. In the ever-evolving sector of pharmacovigilance, EBPs should consider engaging external pharmacovigilance experts for more efficient and cost-effective market expansion plans. Engaging an end-to-end pharmacovigilance provider that has in-depth market regulatory knowledge could help to reduce time and monetary investments while ensuring that relevant processes and actions are in place.