HOW TO NAVIGATE THE TRANSITION TO POST-APPROVAL PHARMACOVIGILANCE

Choosing the Right Partner for End-to-End Commercial Success

Partnering with a contract research organization (CRO) provider during clinical development fills an important role in the product life cycle, providing pharmaceutical companies with pharmacovigilance expertise and support during clinical trials. After product approvals, it can be tempting for companies to remain with their CRO partner; however, the commercial phase of the product life cycle has more mature pharmacovigilance needs that must be met.

For example, unlike post-market safety, pharmacovigilance during clinical trials is extremely controlled, with many factors in the pharmaceutical company's favor, including:

- A designated treatment population, with specific parameters for inclusion and exclusion for treatment.
- A focus on primarily reporting serious adverse events (SAEs), which are delivered to a PV database via one data stream.
- Pharmaceutical companies routinely see trial participants for follow-up questions and information along with health checks that are easily obtained.
- Most of all, the data are clean, complete and manageable.

None of these truths about drug safety persist after receiving market approval, and the question becomes: **Does your CRO have the experience and resources required to bring your product to market and meet complex post-market pharmacovigilance demands throughout commercialization?**

With your product ready to launch and transitioning into the next phase of the life cycle, you need a **commercialization partner that has the team and resources to provide pharmacovigilance excellence** in every life cycle phase.

The Full Picture: Post-Approval Pharmacovigilance Requires a Centralized, Integrated Approach

The next phase of the product life cycle comes with pharmacovigilance challenges that pharmaceutical companies have never experienced before. One significant differentiator is this: In the controlled clinical trial environment, primarily SAEs land in a centralized pharmacovigilance database, and non-SAE reports are scattered across the various clinical data management systems or electronic data capture platforms used at each site. These systems might work well for clinical trials, but post-market pharmacovigilance will be faced with a higher volume of diverse adverse event reports, a disparate array of reporting streams and added regulatory complexity.

These challenges are best met with an approach that compiles all adverse event data – for serious and non-SAEs – in one location, making it easier to achieve regulatory compliance and predict the rate of adverse events in larger treatment populations. The same data could also help research and development teams better predict the safety profile of new therapeutics in the pipeline – but first, pharmaceutical companies need a **holistic view of pharmacovigilance.** Pharmacovigilance throughout commercialization can greatly benefit from a partner that seamlessly integrates expertise with an intuitive end-to-end safety solution powered by machine learning and artificial intelligence.

Executing superior pharmacovigilance practices from clinical trials throughout the product life cycle is both complicated and costly, which is exactly why 60% of pharmaceutical companies decide against independently managing their pharmacovigilance needs and extensive safety data.

Meeting Your Post-market Product's Pharmacovigilance Needs

Moving on from a CRO is hard; but when your drug is ready to go to market, your CRO must have the ability to provide best-in-class pharmacovigilance and data management in this new phase of the product life cycle. At this phase, companies need a commercialization partner with the capability to manage the product's safety profile and transition up to a decade or more of safety data to a new, integrated team and system.

Is your current pharmacovigilance provider practiced with a best-in-class global technology solution that will scale with your product growth strategy?

Consolidate Data to Develop Accurate Insights and Drive Proactive Safety Responses

If you choose multiple commercial services vendors to meet your pharmacovigilance needs, your safety data will be stored in different technology solutions and platforms – resulting in disconnected, inconsistent datasets that are fragmented and incomplete pharmacovigilance insights. Relying on multiple pharmacovigilance vendors will also result in wasted time and resources spent sifting through dispersed safety data, leaving room for crucial errors in safety profile management and emergency response.

By the time a product goes to market, automatic event and product coding quickly become must-haves for pharmacovigilance, and simple systems and many CRO databases may not have that capability. Even with an advanced solution that aggregates and centralizes data into a single database, your pharmacovigilance partner must also have the knowledge and experience to manage this massive data migration project for the next phase of the product life cycle. When outsourcing pharmacovigilance services across disconnected platforms and providers, safety data cannot be efficiently integrated into the product life cycle, increasing the risk of missed safety insights, oversight in safety profiles and failure to use data to its full potential in patient safety and ROI.

A well-qualified commercialization partner will possess the expertise to centralize your data using a modern technology platform that automates and consolidates drug safety operations. LifeSphere Safety, ArisGlobal's unified cloud platform for end-to-end drug safety, is exemplary in these regards. LifeSphere Safety embeds over 30 years of pharmacovigilance industry expertise and the most production-ready intelligent automation available. The platform leverages industry-specific innovations in machine learning and artificial intelligence to enable case processing efficiency gains of 30% or more and delivers real-time insights for signal detection and risk management. These capabilities are essential for addressing the expected post-authorization increase in case volume and leveraging all data from the product life cycle to proactively manage safety profiles.

Synchronously Leverage Safety Data and Pharmacovigilance Expertise Across Commercial Services

Companies often try to transition the same safety management team from clinical trials to post-market, but the product's pharmacovigilance needs become increasingly more complicated in commercialization.

For example, in the post-market setting, information about adverse events and SAEs comes from real-world use by patients and providers. These adverse events may be reported through multiple channels, such as a call center, email/FAX, information from field sales/MSL team members, calls direct from patient or caregiver, or as part of required literature surveillance. With sporadic, sometimes incomplete, post-market safety data, patient information isn't controlled, and there is little to no ability to obtain follow-up information.

To accurately and efficiently track real-world data, pharmaceutical companies need an experienced pharmacovigilance team that can leverage this sophisticated data to analyze and understand incoming patient information and identify adverse events and SAEs. Failure to find and understand these events in the post-market phase will ultimately hurt manufacturer response time as well as provider relationships with pharmaceutical companies and overall patient trust.

Today's Pharmacovigilance Solution for Tomorrow's Lifesaving Treatments

There is one constant to innovation: It never stops. By integrating both pharmacovigilance expertise and real-time predictive intelligence with an end-to-end commercial services provider, pharmaceutical companies can take their safety profile management a step further.

EVERSANA and ArisGlobal are transforming pharmacovigilance services with the power of an end-to-end, integrated services model combined with intelligent data automation. Intelligent automation from ArisGlobal's LifeSphere® Safety platform and EVERSANA's developed commercial services infrastructure – including a suite of trained physicians, post-market safety and regulatory compliance experts, medical information, quality assurance and quality systems – provides seamless, cost-efficient pharmacovigilance practices that deliver clinical and commercial product safety management through machine-learning-enhanced adverse event case processing, signal detection and risk management.

Together, this unified end-to-end drug safety platform and industry-leading commercial services model gives pharmaceutical companies the power to manage pharmacovigilance by holistically, efficiently reviewing compliance and safety throughout the product life cycle.

Speak with one of our pharmacovigilance experts today.