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BREAKING UP IS HARD TO DO: WHEN TO LEAVE YOUR CRO FOR OPTIMIZED PHARMACOVIGILANCE

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It's been an intense year for innovation in the life sciences industry. New technologies, including artificial intelligence, are flooding the market; and the industry's rapid growth is spotlighting the global need to bring pharma's pharmacovigilance practices up to speed across emerging and large-scale companies.

Currently, almost 400,000 clinical studies are happening globally, according to the U.S. National Library of Medicine. Most will take an average of six to seven years to complete, and this is just the beginning for safety data monitoring. Executing superior pharmacovigilance practices from clinical trials throughout the product life cycle is both complicated and costly, which is exactly why 60% of manufacturers decide against independently managing their pharmacovigilance needs and extensive safety data. Too often, pharmacovigilance is further complicated for manufacturers with siloed commercial services and disjointed datasets.

In working with clients, we recognize that manufacturers develop a long-time relationship with contract research organizations (CRO) in clinical trials, and it's tempting to remain with them when entering the next phase of the product's life cycle – but how do you know when it's time to leave your CRO for a partner that not only delivers integrated pharmacovigilance, but also optimizes product safety and data management during the commercial phase?

Manufacturers need to "swipe right" in their search for a pharmacovigilance partner. It's time to entrust your safety needs to a partner that is built for seamless safety profile management and alleviate the burden of managing end-to-end pharmacovigilance alone. Here are three ways to know you've found a partner that will build continuity in drug safety practices for your product.

1 Your partner can consolidate data to develop accurate pharmacovigilance insights.

Moving on from your CRO is hard; but when your drug is ready to go to market, CROs don't have the ability to provide best-in-class pharmacovigilance and data management in this new phase of the product life cycle. It's time for a new partner to manage your safety profile, and you must begin transitioning a decade or more of safety data to a new team and system.

When choosing multiple, disconnected vendors to meet your pharmacovigilance needs, safety data will be stored in multiple technology solutions and platforms – resulting in siloed, inconsistent datasets and fragmented, 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. For the sake of product success and improved patient outcomes, your expansive library of critical data needs to be consolidated in one place beginning in post-market approval to launch and beyond.

2 Your partner drives proactive safety responses with integrated data automation.

With real-time predictive intelligence, manufacturers can process and analyze safety data to **confidently predict key signals** and risk factors, **identify safety issues,** and make recommendations for appropriate product utilization that **maximizes patient outcomes**.

When outsourcing pharmacovigilance services across disconnected platforms and providers, safety data cannot be efficiently integrated into the product life cycle, increasing risk for missed safety insights, oversight in safety profiles, and failure to use data to its full potential in patient safety and ROI. By funneling and saving safety data into one platform built on a foundation of automation and machine learning, manufacturers will have access to the product's entire life cycle of safety data at their fingertips, as well as real-time predictive intelligence to drive their pharmacovigilance practices and ensure they are meeting patient needs.

With an intuitive data platform, manufacturers can also make critical decisions about product life cycle management with increased speed and agility, including decisions about therapeutic area or geographic expansion, predictive safety for targeted population, off-label use and personalized safety in the era of cell and gene therapy.

3 Your partner can synchronously leverage safety data and pharmacovigilance expertise across commercial services.

Manufacturers often try to transition the same safety management team from clinical trials to advanced phases of the product life cycle when the product has more mature pharmacovigilance needs.

For example, during clinical trials, patient information is extremely standardized, while in the post-market setting, information about adverse events (AEs) and serious adverse events (SAEs) comes from real-world use by patients and providers. These AEs may be reported through multiple channels, such as a call center, received via 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, manufacturers need an experienced pharmacovigilance team that can leverage this sophisticated data to analyze and understand incoming patient information and identify AEs 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 manufacturers and overall patient trust.

By integrating both pharmacovigilance expertise and real-time predictive intelligence with an end-to-end commercial services provider,

How To Change Your Pharmacovigilance Model:

Step 1:
Bring data into one platform earlier in the product life cycle.

Step 2:
Take the time to aggregate safety data into one platform, and centralize data with one experienced pharmacovigilance partner.

Step 3:
Set pharmacovigilance goals for desired outputs at the product and portfolio levels.

manufacturers 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. Automated intelligence 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.

Together, this predictive analytics platform and industry-leading commercial services model gives manufacturers the power to manage pharmacovigilance by holistically reviewing compliance and safety throughout the product life cycle.

Don't Compromise Optimal Pharmacovigilance for the Status Quo

We understand that transitioning your product's safety management in new phases of the product life cycle is overwhelming, and there's a lot to consider when searching for your next pharmacovigilance partner. But by graduating your safety profile to one integrated pharmacovigilance team and platform, you can ensure safety data will be consistent, centralized and actionable while also saving millions in time and resources.

With a single source of safety management, you can avoid critical gaps in safety information and focus on delivering what matters most – safer, more effective medicines for patients worldwide.

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About EVERSANA™

EVERSANA is the leading provider of global commercialization services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, providers, channel partners and payers. The company serves more than 500 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences services for a healthier world. To learn more about EVERSANA, visit EVERSANA.COM or connect through LinkedIn and Twitter.