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Trends Shaping the Future of Pharmacovigilance



TRENDS SHAPING THE FUTURE OF PHARMACOVIGILANCE

British journalist, biographer and statesman John Morley stated, “Evolution is not a force but a process.”

In an effort to continuously improve the efficacy of drugs and health outcomes for patients, the healthcare industry gradually evolves to meet changing regulations, make the most of new technologies and communication channels, and cater to individuals and their unique needs. With the evolution of the healthcare industry comes the need to change the way, frequency or guidelines by which product safety is monitored and reported.

While pharmacovigilance has long been a cornerstone of the healthcare industry, more thorough safety documentation and reviews for drug approvals — along with increased warnings and awareness about adverse drug reactions within the last few years — have made drug safety one of the top concerns for consumers and regulators.

These safety concerns have prompted global mandates for submitting significantly more detailed product information, as well as a push for more clinical and safety data transparency. Understanding the trends that are shaping the future of pharmacovigilance will help your business get a head start on ensuring consistent performance with adherence to strict regulatory requirements.

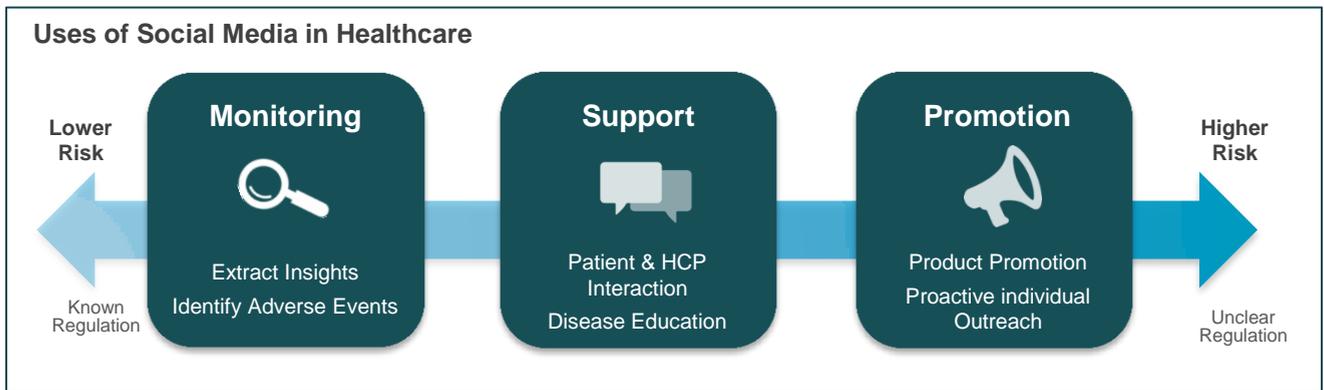
C3i Solutions sees four major trends that are reshaping the world of pharmacovigilance:



SOCIAL MEDIA AND DIGITAL HEALTH

The traditional model of healthcare, with patients taking a passive role in their own health and well-being, is changing. A new standard of patient involvement has evolved. Social media, digital health devices, and mobile applications have made multi-channel health related interactions a part of everyday life.

Social media has become an integral part of healthcare and product safety. More than 40% of consumers say that information found via social media affects the way they deal with their health.¹ Of respondents 18 to 24 years of age, 90% say they would trust medical information shared by others on their social media networks.² Of adults, 47% say they are likely to share their health information on social media sites with doctors, 43% with hospitals, 38% with health insurance companies, 32% with drug companies, and 30% with other patients.³ These statistics illustrate that there is immense value in companies taking a proactive approach to social media monitoring, as well as utilizing social media to provide accurate drug related information to consumers. Additionally, proactive monitoring could provide early warning of new adverse events or clinical insights that help both guide drug development and avoid preventable litigation.



Likewise, consumers are jumping at the opportunity to better track, manage, and improve their well-being through digital health devices and mobile applications. 41% of consumers have a strong interest in remote monitoring devices to check conditions and share information.⁴ And research estimates that as many as 4 million patients will use remote patient monitoring technologies by 2020.⁵

Will the exponential growth of digital health devices become fundamental for delivering high quality care? It stands to reason that proactively monitoring patient health through digital health devices could provide insight into reducing the number and severity of adverse events.

¹ <http://www.adweek.com/socialtimes/files/2012/12/social-media-healthcare.png?red=at>

² <http://searchenginewatch.com/sew/news/2169462/-consumers-social-media-health-care-info-survey>

³ <http://gabi-journal.net/safety-and-toxicity-of-biosimilars-eu-versus-us-regulation.html>

⁴ <https://s-media-cache-ak0.pinimg.com/236x/e5/bf/36/e5bf36c48b3620c9b354fb9de06afdfc.jpg>

⁵ <http://www.gfk.com/news-and-events/press-room/press-releases/pages/gfk-forecasts-51-million-wearables-sold-globally-2015.aspx>

PROACTIVE PHARMACOVIGILANCE

Challenges are bound to arise, regardless of an organization's size, when crafting a global pharmacovigilance strategy. A small company's challenges might include an elevated risk of non-compliance and availability of in-house safety expertise, while a larger company may struggle with creating and maintaining global standard operating procedures (SOPs) across regions and product categories, as well as effective oversight of global resources. For a pharmacovigilance department to be successful, internal practices need to be established in advance and made easily scalable to meet global needs.

Our reactive pharmacovigilance industry is transforming into a proactive, benefit-risk management industry in order to adapt to modern technology and the growing need of consumers to receive immediate and reliable information through various channels.

The consequences of perpetuating a reactive approach can be disastrous – halting a clinical study, delaying drug approval, recalling a marketed drug; as well as brand damage, class action suits, and exorbitant fines. Moving forward, pharmaceutical and biotechnology companies must not only monitor for adverse events, but also proactively assess and manage drug risk throughout a product's lifecycle. Developing a pharmacovigilance risk management plan with a risk minimization action plan (RiskMAP) for high risk products is becoming ever more essential.

INTENSIFYING GLOBAL REGULATORY EXPECTATIONS

The global pharmacovigilance market continually faces intensifying regulatory expectations, tougher inspection systems and an instant need for patient reporting. Organizations are more focused on introducing safer products to patients in a timely manner. As a result of globalization, pharmaceutical companies must meet region specific safety requirements, interpret legal requirements for their individual company structure, and harmonize international laws for different regions. Risk management plans (RMP), pharmacovigilance system master files (PSMF), periodic reports (PSUR, PBRER, PADER), product information, adverse event and adverse drug reaction reporting, drug renewals, signal management, medical literature monitoring - these are simply the basics when considering a pharmacovigilance strategy.

Additionally, intensifying global regulatory expectations mean pharmaceutical companies must adapt and make risk management a centerpiece of global pharmacovigilance operations. The term risk management should not be thought of as mitigating only risks of adverse events, but also in terms of risks to product quality, data integrity and patient privacy.

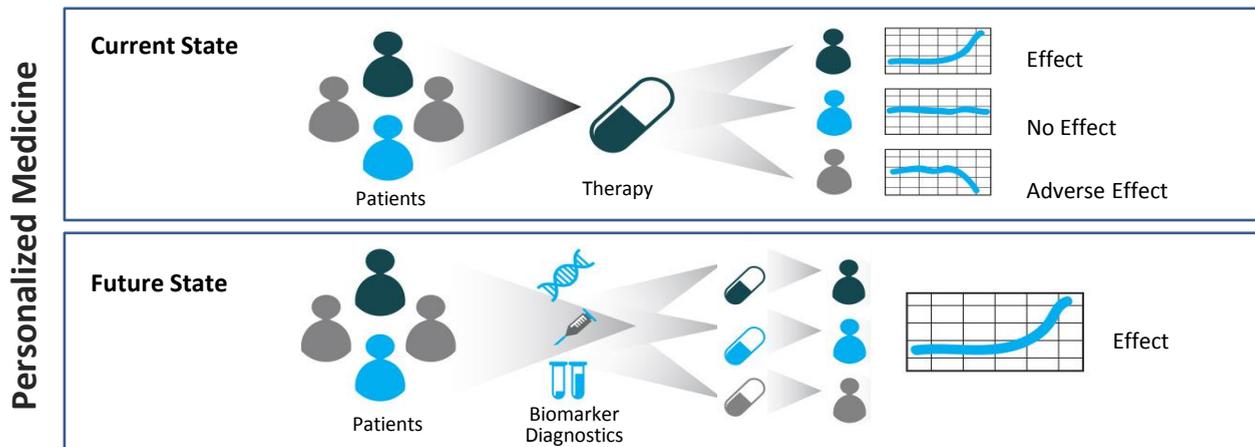
Addressing risks up front will improve risk-benefit outcomes and provides significant progress for public health.

PERSONALIZED MEDICINE AND BIOSIMILARS

Personalized medicine identifies a patient's biological and disease characteristics to tailor specific therapies for an individually optimized benefit-risk balance.

The growth of personalized medicine signals increased benefits, reduced risks, and improved efficacy of many products for individuals. While progress in regenerative medicine and stem cell research offers hope for some of the most personalized products imaginable, this progress also brings to light a new safety paradigm. Different risk profiles should be anticipated due to diverse factors, including genetic variables, which may bring about more adverse drug responses and interactions.

Personalized medicines also require more complex labeling since they might have differing safety and efficacy profiles and dosing requirements in different sub-populations. Currently, there are more than 100 approved drugs with labels that contain information on genomic biomarkers (including gene variants, functional deficiencies, expression changes, and chromosomal abnormalities).



Other pharmacovigilance process complexities arise from biosimilars. As patents expire for well-known biological products, need for safety monitoring of biosimilars increases. The reports submitted for approval of generics are not able to demonstrate the quality, efficacy, and safety of biosimilars since the active substance of a biosimilar is not identical to the active substance of the reference product. In addition, biosimilar manufacturers must conduct their own pharmacovigilance because even the slightest differences between the reference product and the biosimilar impact the efficacy and safety of the product.

Even if similar efficacy is proven in the comparability exercises conducted during biosimilar development, the safety profile might differ from that of the reference product. The particular need for post-marketing safety surveillance is stressed for biosimilars because most biologics, including biosimilars, are used for long-term treatment of chronic diseases. Only effective post-marketing including post-authorization safety studies (PASS) can provide sufficient evidence that a biosimilar safety profile is comparable to the reference product.³

CONCLUSION

Pharmacovigilance continues to play a crucial role in drug development and consumer safety. Being aware of the trends discussed in this eBook and adjusting your company's pharmacovigilance strategy can help support process efficiency and reduce pharmacovigilance process related expenditure. Taking a risk-based approach to compliance planning, execution, and monitoring makes good clinical and business sense in the and highly regulated health care environment.

C3i Solutions, an HCL Technologies Company, is a multi-channel customer engagement services provider, specializing in global, high-touch consumer, patient, and end-user management.

For the past 35 years, our unique, multi-channel approach and experience in highly regulated industries have made us the partner-of-choice for some of the world's most trusted brands.

With a strategic focus on innovation, we excel at protecting our clients' brands, while maximizing productivity and cost efficiency.



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